



**MARYLAND HEALTH
CARE COMMISSION**

**Application for Certificate of Conformance
Non-Primary 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 Non-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 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 September 5, 2014, if a letter of intent was filed by August 1, 2014. 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

CARE

COMMISSION

_____ **MATTER/DOCKET NO.**

_____ **DATE DOCKETED**

Application for Certificate of Conformance to Perform Non-Primary Percutaneous Coronary Intervention

Applicant Information

Applicant Carroll Hospital Center

Street Address 200 Memorial Avenue

City: Westminster County: Carroll State: MD Zip Code: 21157

Mailing Address (if different) Same

City _____ County _____ State _____ Zip Code _____

Medicare Provider Number(s) 21-0033 National Provider Identifier 1912904210

Person to be contacted on matters involving this application:

Name Robert White, MBA, MHA, FACHE

Title Vice-President of Hospital Operations, Professional and Support Services

Address 200 Memorial Avenue

Address _____

City Westminster County Carroll State MD Zip Code 21157

Telephone 410-871-6749 Facsimile _____ E-mail RWhite@carrollhospitalcenter.org

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 X 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 X
If yes, attach an explanation.
- Q3.** Is the applicant accredited by the Joint Commission? Yes X 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 X
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 X
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 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. **See Q6 attachment**
- 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. **See Q7 attachment**

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.

- **2013 Charity Care was \$6,198,891 or 3% of Total Operating Expenses.**
- **Total 2013 Community Benefit was \$18,020,053 or 8.67% of Total Operating Expenses and 71.82% of Net Revenue**

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.

- **NA. CHC is 100% for all measures except door to balloon (DTB) where we are at 96%**

(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.

- **Prior to our Emergent program, patients who presented to our emergency department either via walk-in or via EMS would have to be transferred to other tertiary facilities to receive this service. In many cases, it was taking in excess of 3 hours to get the patient out of our emergency department and to other providers of primary PCI services for treatment.**

(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 PCI service (emergency and elective) to achieve financial viability.

Q11. Are you requesting that the volume requirement of 200 cases be waived?

Yes ___ No X

If 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.

The hospital is confident it will be able to meet the 200 case requirement within the designated two-year time frame. After reviewing the market data provided by the Maryland Healthcare Commission and speaking to referring physicians (both those in primary care and cardiology), the hospital estimates that it will capture 25 percent of the current elective cases being performed on residents living in its primary service area in year one, 30 percent of those cases by year two and 35 percent of those cases in year three. These market share estimates are consistent with CHC's current market share for emergent PCI (Approximately 38%). The hospital's total case estimates were based on combining projected elective cases with our current emergent PCI volumes. We have provided detail of our projections below.

Angioplasty Projections- Elective and Emergent							
Elective Angioplasty							
	Base Year Data	Carroll Hospital Center, Inc Market Share Assumptions			Carroll Hospital Center, Inc Cases (@ Assumed Share)		
City	CY 2013	Year 1	Year 2	Year 3	Year 1	Year 2	Year 3
	Cases						
Finksburg	25	31%	37%	43%	8	9	11
Hampstead	28	24%	30%	35%	7	8	10
Keymar	4	8%	9%	14%	0	0	1
Manchester	24	21%	27%	33%	5	6	8
Mt. Airy	50	7%	8%	13%	4	4	7
New Windsor	15	26%	33%	38%	4	5	6
Sykesville	78	25%	32%	37%	20	25	29
Taneytown	15	30%	35%	40%	5	5	6
Union Bridge	13	12%	17%	22%	2	2	3
Upperco	3	12%	17%	22%	0	1	1
Westminster	141	33%	38%	43%	47	54	61
Woodbine	<u>17</u>	29%	34%	37%	5	6	6
Total Market Area	413	<u>25%</u>	<u>30%</u>	<u>35%</u>	<u>105</u>	<u>126</u>	<u>147</u>
Projected Cases Adjusted by 50% - Represents Jan 1, 2015 Start					<u>52</u>		
Plus Current Emergent PCI Cases					80	80	80
Total Projected Annual Volumes - Elective and Emergent Combined					132	206	227
Cumulative Totals					132	338	564

(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 X 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.
Please see addendum Q15 for signed letter of commitment.

(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 June 30, 2014.
No patients received thrombolytic therapy due to service being unavailable.

(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 June 30, 2014.

Reporting Period: 06/01/13 – 06/31/14
 From (mmddyy) To (mmddyy)

CCL Room	Days and Hours of Operation							
	Hours	Mon	Tue	Wed	Thu	Fri	Sat	Sun
1	Regular:	9.5	9.5	9.5	9.5	9.5	0	0
	On-Call:	14.5	14.5	14.5	14.5	14.5	24.0	24.0
3	Regular:	9.5	9.5	9.5	9.5	9.5	0	0
	On-Call:	14.5	14.5	14.5	14.5	14.5	24.0	24.0

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 June 30, 2014.

Room	CCL Downtime			
	Date		Duration (Hours)	Reason Unavailable
	Begin	End		
1	06/03/13	06/03/13	2.0	Preventative maintenance
1	06/06/13	06/06/13	0.5	ECG not displaying in room. Fixed by BioMed
1	06/07/13	06/07/13	0.4	Knob on side of table control broke off. Replaced by BioMed
1	06/13/13	06/13/13	1.3	Broken support cable on monitor
1	09/27/13	09/27/13	4.0	Preventative maintenance
1	12/02/13	12/02/13	2.0	Preventative maintenance
1	12/16/14	12/16/14	4.0	Preventative maintenance follow up

Room	CCL Downtime			
	Date		Duration (Hours)	Reason Unavailable
	Begin	End		
1	03/25/14	03/25/14	4.0	Preventative maintenance
1	06/17/14	06/17/14	4.0	Preventative maintenance
2	08/15/13	08/15/13	4.0	Preventative maintenance
2	06/13/13	06/13/13	0.3	EKG not showing up on images. Fixed by BioMed
2	09/18/13	09/18/13	2.4	Exposed wire on foot pedal. Fixed by BioMed
2	12/24/13	12/24/13	1.4	Imaging processing error.
2	02/03/14	02/03/14	2.0	Lead shield support frozen
2	02/20/14	02/20/14	8.0	Preventative maintenance
2	05/19/14	05/19/14	2.0	Preventative maintenance
2	05/27/14	05/27/14	4.0	Cooling tower contaminated. Found during PM

(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 X 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 Staff on Team	Number of Staff	Call Rotation	Response Time
MD	1	Every 4th night and every 4th wkd	45 minutes
Fellow			
Nurses		No change	
Technicians		No change	
Other (specify)			
Nurse Tech		No Change	

- 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:

08/31/14

(mmddyy)

	Number/FTEs	Cross-Training (S/C/M)
Physician	4	
Nurse	6.2 (FTE)	C/M
Technician	4.8 (FTE)	S/C/M
Nursing Patient Care Tech	1	C

(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.

Quarter Ending	Number of STEMI Patients*	Number of STEMI Patients Receiving Primary PCI	STEMI Patients* with DTB Time < 90 Minutes ²	
			Number	%
Qtr. 3 ,2013	38	27	25	93%
Qtr. 4,2013	21	17	11	65%
Qtr. 1,2014	22	18	16	89%
Qtr. 2,2014	26	20	20	100%

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
Qtr. 3 ,2013	0		
Qtr. 4,2013	0		
Qtr. 1,2014	0		
Qtr. 2,2014	0		

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 June 30, 2014? Yes _____ No X

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.

In the fourth (4) quarter of 2013, the hospital did not meet the requirement of DTB of 90 minute or less 75% of the time. The hospital’s percentage was 65%. Of the 17 patients receiving Primary PCI, six (6) did not meet the required 90 minute DTB. The following are the times, reasons and what steps the hospital is taking to assure we meet the requirements in the future.

- 10/12/13 DTB time was 91 minutes. Difficulty accessing lesion.
- 10/12/13 DTB time was 98 minutes. There was difficulty in getting an informed consent.
- 10/20/13 DTB time was 105 minutes. Delay due to clinician having a difficult time with accessing the culprit lesion.
- 11/09/13 DTB time was 147 minutes. Patient arrived in ED needing to be intubated and placed on IABP prior to procedure.
- 12/08/13 DTB time was 106 minutes. Patient arrested in Cath Lab and had to be resuscitated.
- 12/08/13 DTB time was 91 minutes. Patient arrested in ED and was also intubated there prior to arriving to Cath lab.
- **In every case but two (2), the patient were walk in patients. Carroll Hospital Center is actively reminding the community to call 911. This is done through articles in the papers, and though a local radio Health Chat program which the hospital regularly participates in. We feel patient time would decrease if patients utilize EMS for**

transport. The EMS administer first contact care and can also activate the STEMI from the field which will also decrease DTB times. One of the patients was done radially. Difficult lesions are problems that we try to deal with by having an assortment of catheters and wires available for the Interventionalist. For delays due to consents, the hospital's STEMI review committee has discussed different ways to contact family members and which physician in hospital will be responsible for each consent. This also was the lowest volume quarter of the four.

(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.
See addendum Q23 for letter of commitment.

(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.

Carroll Hospital Center began contracting with Q-Centrix, for quality measures outsourcing specifically for the Cath/PCI and ACTION Registry data abstraction back in May of 2014. The company has assigned a team of 3 abstractors under one manager to oversee the work processes.

Carroll Hospital Center has dedicated a 0.75 FTE to AMI core measure abstraction and other duties related to data collection, management, reporting, and coordination with quality improvement efforts. This position provides oversight and coordination of activities involving the registries such as data validation, follow-up with providers, and support to the functions of the STEMI Committee. Prior to contracting with Q-Centrix, this person also did all the registry abstraction.

(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.
Not Applicable. Physicians only cover call at one hospital per shift.

(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 June 30, 2014. **See addendum Q26 for staff education**

Continuing Educational Plan:

The educational plan will utilize a frame work that not only supports skills based practice, but will support the application of knowledge, evidence and science. This will be accomplished through interactive computer based training/ classroom and unit orientation. The specific educational focus will be as follows:

- Attendance to the monthly case review offered by the Cardiac Cath Lab Case Review Committee chaired by interventional cardiologist. Staff will participate in films review, appropriate treatment and patient outcomes.
- Monthly Educational Staff Meetings will include STEMI/NSTEMI education, equipment competency, procedural/ pharmacological updates, regular Intra- Aortic Balloon Pump (IABP) seminars, as well as any other identified educational needs.
- Attendance to the Critical Care Consortium offered every other month. (Essential for new staff to attend)

Additionally, staff members participate in annual mandatory competency validation. Competencies are identified through the performance improvement process and a review of high risk/low events and any adverse patient outcomes.

Education Overview

Course	Description
Basic and Advance ECG Course	<p>Designed for staff members caring for monitored patients to help them recognize, identify and interpret basic and advanced cardiac rhythms.</p> <p>Concentration:</p> <ul style="list-style-type: none"> • Relationship of normal cardiac waveform components to anatomy and physiology of the heart • Normal Conduction • Proper electrode and lead placement • Bedside monitoring • Rhythm interpretation normal vs abnormal (Atrial, Junctional, Ventricular, Heart Blocks, Pulseless Electrical Activity) • Cardiac Rhythm Devices <p>An examination is required for successful completion of the course.</p>

Education Overview (cont.)

Course	Description
<p>12 Lead ECG</p>	<p>Understanding the of the basic arrhythmia interpretation. Emphasis on:</p> <ul style="list-style-type: none"> • Correct Lead placement • Vector, Axis and R wave progression • Systematic approach to 12 Lead ECG interpretation • Recognize 12 Lead waveform changes in relation to ischemia and injury • Distinguish between old and new Myocardial infarction (MI) • Identify/Recognize the impact of Bundle Branch Block associated with MI
<p>Critical Care Consortium</p> <p>Unit Orientation</p>	<p>(See attached Outline Q26) This course is an introduction of core critical care concepts for nurses entering critical care practice. It provides a theoretical base for clinical decisions made in critical care units.</p> <p>Orientation to the units are designed to meet the specific needs of the staff. Orientation will consists of but not limited to the following:</p> <ul style="list-style-type: none"> • Advanced Hemodynamic monitoring (i.e. Pulmonary Artery, Central Venous, Cardiac Output, IABP, Arterial lines) • Coronary Angiography • Information regarding stents, balloons, interventional wires and diagnostic/guiding catheters • Intracoronary drugs, prep, administration and outcomes • Post procedure care • Administration of Vasoactive medications

(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 PCI, 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 X No

If yes, please provide a copy. If no, provide either a new agreement or a signed and dated amendment to an existing agreement. **See addendum Q27 for agreement**

(15) A hospital shall maintain its agreement with an advanced cardiac support emergency medical services provider that guarantees arrival of the air or ground ambulance at the applicant hospital within 30 minutes of a request for non-primary PCI patient transport by the applicant.

- 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 X 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.
Please see addendum Q28 for transport agreement.

(16) 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.

Q29. Please use Form C to report attendance at the interventional case review meetings.

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 June 30, 2014.

Name and Credential	Title	Date of Cardiac Catheterization Laboratory Case Review (mmdyy)											
		072413	082813	092513	102313	112713	122513	012214	022614	032614	042314	052814	062514
<i>Physicians</i>													
Dr. David Zimrin	Medical Director	X		X	X		N	X		X	X		X
Dr. Anuj Gupta	Interventionalist		X			X	O						
Dr. Mark Vesely	Interventionalist												
Dr. Steve Kim	ED Physician	X	X			X	M	X	X	X	X	X	X
Dr. Srivastava	Interventionalist						E						
Dr. Mark Olszyk	VP, Medical Affairs				X	X	E		X				
Dr. Rex Matthew	ED Physician				X		T						
Dr. Daniel Grove	CCU Intensivist											X	
<i>Nurses</i>													
Janice Toth	Quality Review	X	X	X	X	X	N	X	X	X	X	X	X
Colleen Hordesky	ED RN	X	X	X		X	G	X	X	X	X	X	X
Ivy Brown	Nurse Educator	X	X	X								X	X
Krista Johnson	CV Nurse	X	X		X	X	C						
Bonny Kindt	CV Nurse						H	X	X	X			X
Cheryl Perry	Nurse Educator		X	X		X	R				X		X
Leanne Bonds	CCU Manager	X	X	X	X		I						
Jim Ridge	CCU Mgr/Exec. Dir.					X	S	X	X	X	X		X
<i>Technicians</i>													
Tony Pinson	CV Service Manager	X	X	X	X	X	M	X	X		X	X	X
Cole Boone	CV Lab Team Leader						A						X
							S						
<i>Other</i>													
Mark Maslow	Exec Director CVSL	X	X	X	X	X	D	X	X	X	X	X	
Libby Lieberman	EMS Liaison	X			X	X	A		X	X	X	X	X
Trisha Kokoski	Pharmacist	X		X	X	X	Y	X	X	X	X	X	
Amy Krohn	Administrative Asst.											X	

(17) 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.

Q30. Please use Form D to report attendance at the multiple care area group meetings.

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 June 30, 2014.

Name and Credential	Title	Date of Cardiac Catheterization Laboratory Case Review (mmddyy)											
		072413	082813	092513	102313	112713	122513	012214	022614	032614	042314	052814	062514
<i>Physicians</i>													
Dr. David Zimrin	Medical Director	X		X	X		N	X		X	X		X
Dr. Anuj Gupta	Interventionalist		X			X	O						
Dr. Mark Vesely	Interventionalist												
Dr. Steve Kim	ED Physician	X	X			X	M	X	X	X	X	X	X
Dr. Srivastava	Interventionalist						E						
Dr. Mark Olszyk	VP, Medical Affairs				X	X	E		X				
Dr. Rex Matthew	ED Physician				X		T						
Dr. Daniel Grove	CCU Intensivist											X	
<i>Nurses</i>													
Janice Toth	Quality Review	X	X	X	X	X	N	X	X	X	X	X	X
Colleen Hordesky	ED RN	X	X	X		X	G	X	X	X	X	X	X
Ivy Brown	Nurse Educator	X	X	X								X	X
Krista Johnson	CV Nurse	X	X		X	X	C						
Bonny Kindt	CV Nurse						H	X	X	X			X
Cheryl Perry	Nurse Educator		X	X		X	R				X		X
Leanne Bonds	CCU Manager	X	X	X	X		I						
Jim Ridge	CCU Mgr./Exec. Dir.					X	S	X	X	X	X		X
<i>Technicians</i>													
Tony Pinson	CV Service Manager	X	X	X	X	X	M	X	X		X	X	X
Cole Boone	CV Lab Team Leader						A						X
							S						
<i>Other</i>													
Mark Maslow	Exec Director CVSL	X	X	X	X	X	D	X	X	X	X	X	
Libby Lieberman	EMS Liaison	X			X	X	A		X	X	X	X	X
Trisha Kokoski	Pharmacist	X		X	X	X	Y	X	X	X	X	X	
Amy Krohn	Administrative											X	

(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.
See addendum Q31 for agreements

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 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: **Robert White** _____

Title: **Vice President, Operations** _____

Date: **08/29/2014** _____

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. Use of Funds

1. Capital Costs:

a.	<u>New Construction</u>	\$	_____
(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.	<u>Renovations</u>		
(1)	Building	\$	_____
(2)	Fixed Equipment (not included in construction)		_____
(3)	Architect/Engineering Fees		_____
(4)	Permits, (Building, Utilities, Etc.)		_____
	SUBTOTAL	\$	_____
c.	<u>Other Capital Costs</u>		
(1)	Major Movable Equipment		_____
(2)	Minor Movable Equipment		<u>170,000</u>
(3)	Contingencies		_____
(4)	Other (Specify)		_____
	TOTAL CURRENT CAPITAL COSTS	\$	<u>170,000</u>
	(a - c)		
d.	<u>Non-Current Capital Cost</u>		
(1)	Interest (Gross)	\$	_____
(2)	Inflation (state all assumptions, including time period and rate)	\$	_____
	TOTAL PROPOSED CAPITAL COSTS	\$	<u>170,000</u>
	(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)		_____
	TOTAL (a - j)	\$	_____

3.	<u>Working Capital Startup Costs</u>	\$	_____
	TOTAL USES OF FUNDS (1 - 3)	\$	<u>170,000</u>

B. Sources of Funds for Project:

1.	Cash		<u>170,000</u>
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)		_____
	TOTAL SOURCES OF FUNDS (1-9)	\$	<u>170,000</u>

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.

CY of FY (Circle)	Two Most Actual Ended Recent Years		Current Year Projected	Projected Years (ending with third full year in which the applicant projects provision of npPCI services)			
	2013	2014	2015	2016	2017	2018	20__
1. Revenue ('000s)							
a. Inpatient Services	\$1,854	\$1,891	\$2,159	\$2,473	\$2,562	\$2,646	
b. Outpatient Services			\$192	\$466	\$544	\$617	
c. Gross Patient Services	\$1,854	\$1,891	\$2,351	\$2,939	\$3,106	\$3,265	
2. Adjustments to Revenue							
d. Allowance for Bad Debt	\$40	\$58	\$61	\$76	\$80	\$84	
e. Contractual Allowance	\$182	\$225	\$280	\$350	\$370	\$389	
f. Charity Care	\$45	\$25	\$42	\$53	\$56	\$59	
g. Net Patient Services	\$1,587	\$1,583	\$1,968	\$2,460	\$2,600	\$2,733	
h. Other Operating	\$0	\$0	\$0	\$0	\$0	\$0	
i. Net Operating Revenue	\$1,587	\$1,583	\$1,968	\$2,460	\$2,600	\$2,733	

Revenues and Expenses – PCI Services	Two Most Actual Ended Recent Years		Current Year Projected	Projected Years (ending with third full year in which the applicant projects provision of npPCI services)			
	CY or FY (Circle)	2013		2014	2015	2016	2017
2. Expenses (000's)							
a. Salaries, Wages, and Professional Fees, (including fringe benefits)	\$1,070	\$1,065	\$1,220	\$1,402	\$1,457	\$1,510	
b. Contractual Services	\$13	\$14	\$17	\$22	\$24	\$25	
c. Interest on Current Debt	\$0	\$0	\$0	\$0	\$0	\$0	
d. Interest on Project Debt	\$0	\$0	\$0	\$0	\$0	\$0	
e. Current Depreciation	\$64	\$64	\$64	\$64	\$64	\$64	
f. Project Depreciation	\$0	\$0	\$12	\$24	\$24	\$24	
g. Current Amortization	\$0	\$0	\$0	\$0	\$0	\$0	
h. Project Amortization	\$0	\$0	\$0	\$0	\$0	\$0	
i. Supplies	\$343	\$353	\$568	\$863	\$945	\$1,025	
j. Other Expenses (Specify)	\$0	\$0	\$0	\$0	\$0	\$0	
k. Total Operating Expenses	\$1,490	\$1,496	\$1,883	\$2,375	\$2,514	\$2,648	
3. Income							
a. Income from Operation	\$98	\$87	\$85	\$85	\$85	\$85	
b. Non-Operating Income	\$0	\$0	\$0	\$0	\$0	\$0	
c. Subtotal	\$98	\$87	\$85	\$85	\$85	\$85	
d. Income Taxes	\$0	\$0	\$0	\$0	\$0	\$0	
e. Net Income (Loss)	\$98	\$87	\$85	\$85	\$85	\$85	

Revenues and Expenses – PCI Services	Two Most Actual Ended Recent Years		Current Year Projected	Projected Years (ending with third full year in which the applicant projects provision of npPCI services)			
	CY of FY (Circle)	2013		2014	2015	2016	2017
4. Patient Mix:							
A. Percent of Total Revenue							
1) Medicare	30%	42%	50%	50%	50%	50%	
2) Medicaid	6%	14%	10%	10%	10%	10%	
3) Blue Cross	20%	16%	17%	17%	17%	17%	
4) Commercial Insurance	43%	26%	22%	22%	22%	22%	
5) Self-Pay	1%	2%	1%	1%	1%	1%	
6) Other (Specify)	0%	0%	0%	0%	0%	0%	
7) TOTAL	100%	100%	100%	100%	100%	100%	
B. Percent of PCI Cases (as applicable)							
1) Medicare	26%	43%	50%	50%	50%	50%	
2) Medicaid	8%	15%	10%	10%	10%	10%	
3) Blue Cross	23%	15%	17%	17%	17%	17%	
4) Commercial Insurance	42%	26%	22%	22%	22%	22%	
5) Self-Pay	1%	1%	1%	1%	1%	1%	
6) Other	0%	0%	0%	0%	0%	0%	
7) TOTAL	100%	100%	100%	100%	100%	100%	

Financial Projection Assumptions (Support for Form B)

- I. **Volume Assumptions:** The table below provides further detail regarding both historical and projected PCI cases (emergent and elective) for Carroll Hospital Center through FY 2018.

	<u>2 Most Recent Years</u>		<u>Current</u>	<u>Projection Period (3 Full Years)</u>		
	<u>FY '13</u>	<u>FY '14</u>	<u>FY '15</u>	<u>FY '16</u>	<u>FY '17</u>	<u>FY '18</u>
<u>Caseload</u>						
<u>Inpatient</u>						
Emergent	77	80	80	80	80	80
Elective	-	-	18	44	51	58
Total	77	80	98	124	131	138
<u>Outpatient</u>						
Emergent	-	-	-	-	-	-
Elective	-	-	34	82	96	109
Total	-	-	34	82	96	109
<u>Total</u>						
Emergent	77	80	80	80	80	80
Elective	-	-	52	126	147	167
Total	77	80	132	206	227	247

II. Incremental Operating Impact due to Market Share Growth: Carroll Hospital Center participates in a highly bundled form of payment known as Total Patient Revenue (TPR) system that provides a fixed revenue budget for hospital services. This revenue budget incorporates all payors and is not adjusted for volume. Prior to Fiscal Year 2014, CHC was one of ten Maryland hospitals to operate under this system. During 2014, and coinciding with a new Medicare Waiver agreement, the majority of the remaining Maryland hospitals have also converted to a “fixed” revenue budget (Global Budgeted Revenue or GBR) system implemented by the Health Services Cost Review Commission (HSCRC). The industry and the HSCRC are currently evaluating methodologies to adjust budgeted revenue targets in order to equitably recognize changes in market share (ie....shifts in volume away from one hospital to another hospital). For purposes of the financial projections included with this application, CHC has assumed a 50% realization rate of additional revenues generated from volumes shifts to CHC attributable to elective angioplasty cases. CHC has also assumed a 50% variable cost factor to estimate incremental expense growth associated with these cases. The table below provides further illustration of these assumption on operating income.

	<u>Current</u> <u>Year</u>	<u>Projection Period (3 Full Years)</u>		
	<u>FY '15</u>	<u>FY '16</u>	<u>FY '17</u>	<u>FY '18</u>
<u>Cases Shifted to CHC</u>				
Inpatient	18	44	51	58
Outpatient	34	82	96	109
Total	52	126	147	167
<u>Net Revenue Per Case</u>				
Inpatient	\$ 20,280	\$ 20,280	\$ 20,280	\$ 20,280
Outpatient	\$ 9,537	\$ 9,537	\$ 9,537	\$ 9,537
Incremental Revenue (000's)	\$ 689	\$ 1,674	\$ 1,950	\$ 2,216
Realization (Est.)	<u>50%</u>	<u>50%</u>	<u>50%</u>	<u>50%</u>
Incr. Rev. Realized (000's)	\$ 345	\$ 837	\$ 975	\$ 1,108
Less: Variable Costs (50%)	\$ (345)	\$ (837)	\$ (975)	\$ (1,108)
Operating Impact	<u>\$ -</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ -</u>

- III. **Adjustments to Gross Revenue:** Adjustments to gross revenue for bad debt, contractual allowances and charity care have been estimated at rates consistent with prior year levels. CHC has assumed an overall adjustment/allowance rate of 16.3% of revenue throughout the projection period.
- IV. **Variable/Incremental Expense Assumptions:** As described above, CHC has assumed overall incremental expense growth of \$1.1 million by the end of the projection period. This represents 50% of revenue growth (\$2.2 million) before application of realization factor assumptions. The table below highlights revenue and expense growth by the end of the projection period (FY 2018).

	Base Year		Cumm.	
	FY '14	FY '18	Chg.	% Chg
	(Adj for Inflation)			
Total Cases	80	247	167	209%
<u>Net Revenue (000's)</u>				
Net Revenue	\$ 1,625	\$ 3,841	\$ 2,216	136%
Less: Realization Afactor	\$ -	\$ (1,108)	\$ (1,108)	
Net Revenue (Realized)	\$ 1,625	\$ 2,733	\$ 1,108	68%
<u>Expenses (000's)</u>				
Salaries,Benefits,Fees	\$ 1,096	\$ 1,510	\$ 414	38%
Supplies	364	1,025	661	182%
All Other	80	113	33	41%
Total	\$ 1,540	\$ 2,648	\$ 1,108	72%
Operating Income	\$ 85	\$ 85		

Note: FY '14 adjusted for FY '15 revenue inflation (2.5%) and expense inflation (2.8%)

- V. **Revenue and Expense Inflation:** All revenue and expense figures are presented in current dollars beginning with Fiscal Year 2015. Fiscal Year 2015 (current year figures) includes revenue and expense inflation factors of approximately 2.5% and 2.8% respectively.

