

CARDIAC CATHETERIZATION

STANDARDS

I. DEFINITIONS

A. Cardiac Catheterization Procedure: Any cardiac procedure, including diagnostic, therapeutic, and electrophysiology studies, as applicable, performed on a patient during a single session in a Cardiac Catheterization laboratory or a multi purpose special radiological room. Cardiac Catheterization is a medical diagnostic or therapeutic procedure during which a catheter is manipulated by a physician to travel along the course of the blood vessel into the chambers or vessels of the heart. X-rays and an electronic image intensifier are used as aides in placing the catheter tip in the desired position. When the catheter is in place, the physician is able to perform various diagnostic studies and/or therapeutic procedures in the heart.

B. Cardiac Surgery: Surgery on the heart or major blood vessels of the heart including both open and closed heart surgery.

C. Dedicated Cardiac Catheterization Laboratories: Laboratories exclusively dedicated to cardiac procedures.

D. Diagnostic Cardiac Catheterization: Diagnostic Cardiac Catheterization is a classification of invasive procedures in which a slender tube is passed into a peripheral vein or artery, through the blood vessels, and into the heart. These procedures permit study of the heart chambers and the arteries supplying the heart to diagnose illness or

disease. Facilities that do not have Open Heart Surgery capabilities may perform Diagnostic Cardiac Catheterization procedures on carefully screened patients. High-risk patients are referred to facilities capable of caring for more complicated patients. The capacity of a Diagnostic Cardiac Catheterization laboratory is 1,250 cases per year, based on five procedures per day for 250 days.

E. Freestanding Laboratory: A Cardiac Catheterization laboratory which is not on the campus of an acute care facility.

F. Mobile Cardiac Catheterization Laboratory: A Cardiac Catheterization laboratory used for diagnostic procedures and which typically travels between two or more acute care facilities.

G. Non-Dedicated Cardiac Catheterization Laboratories: Laboratories that provide, but are not limited to, cardiac procedures. A Non-Dedicated Cardiac Catheterization laboratory must also have the ability to perform radiological arteriography.

H. Percutaneous Coronary Intervention: The placement of an angioplasty guide wire, balloon, or other device into a coronary artery for the purpose of coronary revascularization.

I. Primary (Emergency) Percutaneous Coronary Intervention (Primary PCI): For the purposes of these Standards, a PCI performed within 120 minutes for emergency acute myocardial infarction (AMI) patients seen in the emergency room (ER) with confirmed ST elevation or new left bundle branch block.

J. Procedure: For purposes of these Standards, the terms “procedure”, “case”, or “patient” mean one visit to the Cardiac Catheterization laboratory by one patient. Although, two or more procedures may be performed, it shall be counted as one (1) case/procedure/patient.

K. Therapeutic Cardiac Catheterization: Therapeutic Cardiac Catheterization is a classification of invasive procedures in which a slender tube is passed into a peripheral vein or artery, through the blood vessels, and into the heart to treat and resolve anatomical and/or physiological problems in the heart. These procedures are intended primarily for the treatment of cardiac illness and disease. The term includes, but is not limited to: percutaneous coronary intervention (PCI), percutaneous transluminal coronary angioplasty (PTCA), atherectomy, stent, laser, cardiac valvuloplasty, balloon atrial septostomy, or catheter ablation.

II. CURRENT INVENTORY

The West Virginia Health Care Authority (Authority) shall provide to each applicant a current inventory of existing Cardiac Catheterization laboratories within its service area. The inventory will identify each device as either stationary or mobile.

III. DIAGNOSTIC CARDIAC CATHETERIZATION NEED METHODOLOGY

A. These standards are applicable to Dedicated, Non-Dedicated, Freestanding and Mobile Diagnostic Cardiac Catheterization laboratories. In conjunction with the

specific standards outlined below, the need for new or additional Diagnostic Cardiac Catheterization capacity within the region shall be determined on the basis of:

1. The need of the population to be served; and
2. The utilization and capacity of existing equipment in the applicant's study area, as described in Subsection E, below.

B. For applicants proposing the initiation of Diagnostic Cardiac Catheterization services, the study area for Cardiac Catheterization services consists of the county of proposal and any county significantly impacted.¹ A significantly impacted county is a county:

1. Wherein at least 25% of the residents rely on the acute care services in the county of proposal; or,
2. A county that generates at least 10% of the applicant's acute care patient load.

C. For existing providers, proposing additional Diagnostic Cardiac Catheterization laboratories, the study area consists of the county of proposal and any county significantly impacted¹. For an existing provider of Cardiac Catheterization services, a significantly impacted county is a county:

¹A significantly impacted county may be a county outside West Virginia. The population projections for out-of-state counties must be based on authoritative sources. In addition, using authoritative sources, applicants shall document the location, description and utilization of all other Cardiac Catheterization laboratories in the proposed study area.

1. Wherein at least 25% of the residents rely on the Cardiac Catheterization services in the county of proposal; or,
2. A county that generates at least 10% of the applicant's Cardiac Catheterization load.

D. For applicants proposing the initiation or expansion of Cardiac Catheterization services, the following population based need methodology must be used:

Projected Study Area Population

(population age cohort proposed to be served by the applicant).

The applicant should include the 0-18 years population only if the applicant proposes to accept pediatric patients.

X

The most recent three-year average West Virginia Use Rate measured by the number of Diagnostic Cardiac Catheterization cases performed for inpatients.

The applicant must submit documentation of the use rates proposed.

Once the number of inpatient Diagnostic Cardiac Catheterizations are calculated, the applicant must adjust the number of cases by applying an adjustment factor for outpatient cases based on the most recent three years as reported on Worksheet 4A of the Uniform Financial Report, or conduct a survey of all facilities providing Diagnostic Cardiac Catheterization for the most recent three years.

Once the inpatient and outpatient projected Diagnostic Cardiac Catheterization cases are calculated, the applicant must subtract the number of Diagnostic Cardiac

Catheterization cases performed by existing providers located in the study area, on residents of the study area in Cardiac Catheterization laboratories in the study area to project the unmet need for Cardiac Catheterization services. Provided, if the applicant is proposing the initiation of Diagnostic Cardiac Catheterization services; is licensed for 175 or more acute card beds; and, provides a full array of secondary level acute care services, it is not required to subtract the number of Diagnostic Cardiac Catheterization cases performed by existing providers in the study area.

Although there may not be an existing Cardiac Catheterization laboratory in the applicant's study area, the applicant cannot realistically expect to capture 100% of the cases projected for the study area. Some patients will not be appropriate for a Diagnostic Cardiac Catheterization at a diagnostic only facility due to their health status; other patients will prefer to have a Diagnostic Cardiac Catheterization performed at a facility that has Therapeutic Cardiac Catheterization and Cardiac Surgery capabilities. Therefore, the projected number of cases for the study area must be adjusted to reflect the number of cases the applicant will capture from the study area.

If there are no existing Cardiac Catheterization laboratories in the applicant's study area, the applicant must adjust the projected number of cases to reflect a realistic capture rate for the applicant's facility. The applicant may use the average of the facility's most recent three-year market share of MDC-5 (Major Diagnostic Category –5, diseases and disorders of the circulatory system) discharges in its proposed study area, or the applicant may adjust the projected cases based on the average market share for Diagnostic Cardiac Catheterization cases of all diagnostic only Cardiac Catheterization providers

within the state for the most recent three-year period. Documentation of the adjustment factor used must be submitted by the applicant.

If the applicant is unable to obtain reliable utilization information on Cardiac Catheterization laboratories located in the applicant's out-of-state study area, the applicant shall subtract the minimum volume of 300 cases per Cardiac Catheterization laboratory.

E. Applicants proposing the initiation, replacement, or expansion of Cardiac Catheterization laboratories shall meet the applicable standards below:

1. New Providers of Diagnostic Cardiac Catheterization Services: Applicants proposing the initiation of Diagnostic Cardiac Catheterization services must demonstrate the following:
 - a. A volume of 300 cases annually must be projected by the end of the third year of operation; and,
 - b. All other Cardiac Catheterization laboratories located in study area counties in West Virginia must have completed 625 cases in the preceding twelve-month period (or an average of 625 per laboratory in a facility with more than one laboratory). In the case of Non-Dedicated Cardiac Catheterization laboratories in the study area, each laboratory must have completed 300 cases in the preceding twelve-month period. However, if any other provider of Cardiac Catheterization services in the study area has failed to reach this threshold within four years of receiving Certificate of Need

approval to initiate Cardiac Catheterization services, the presence of that provider shall not preclude the initiation of Cardiac Catheterization services by the applicant; or

c. If the applicant is licensed for 175 or more acute care beds and provides a full array of secondary level acute care services, it is not required to subtract the number of Diagnostic Cardiac Catheterization cases performed by existing providers located in the study area.

IV. THERAPEUTIC CARDIAC CATHETERIZATION SERVICES NEED METHODOLOGY

A. Introduction:

Since September 1, 2003, the West Virginia Medical Institute (WVMI), on behalf of the West Virginia Health Care Authority, has reviewed quality and utilization of Therapeutic Cardiac Catheterization procedures performed without on-site cardiac surgical coverage for three West Virginia hospitals as part of a demonstration pilot project. The purpose of the pilot project was to evaluate the implementation of this service on a statewide basis.

WVMI compared performance among facilities as reported to the national norms derived from the American College for Cardiology's National Cardiovascular Data Registry (NCDR). Results of the study suggested that complication rates were less than the national comparison rates for all indicators studied; there were no distinctive patterns or trends of deaths or other complications which appeared sporadic; interventional cardiologic

procedures performed in West Virginia facilities that do not have on-site Cardiac Surgery have similar or lower rates of complications as in comparable facilities nationally; and medical record audits in the pilot facilities generally show as good agreement with data submitted to the NCDR as they would expect.

In West Virginia, there are only six providers that offer Cardiac Surgery services: Charleston Area Medical Center, St. Joseph's Hospital, Wheeling Hospital, Monongalia General Hospital, West Virginia University Hospital, and St. Mary's Medical Center. Therefore, most patients experiencing an acute myocardial infarction (AMI) present to a community hospital. In order to receive PCI, an emergency transfer must occur. This transfer may take well in excess of the time in which all experts agree is the "golden hour". Acute coronary intervention is now the treatment of choice with AMI and high risk acute coronary syndromes. Since this is the best treatment available, it is important to make it more available in community hospitals where most of the patients are currently presenting for treatment.

B. Criteria

1. Providers with current CON approval to provide Cardiac Surgery services shall not be required to undergo CON review to provide Therapeutic Cardiac Catheterization services.
2. Applicants proposing to perform Primary PCI without on-site Cardiac Surgery services shall demonstrate all of the following:

- a. There are a minimum of two interventional cardiologists to perform the Primary PCI and they are experienced interventionalists who have performed at least 75 interventions annually during the most recent 24 month period preceding the date the application was filed.
- b. The nursing and technical catheterization laboratory staff must be experienced in handling acutely ill patients and comfortable with interventional equipment. They must have acquired experience in dedicated interventional laboratories at a surgical center. They participate in a 24-h, 365-day call schedule.
- c. The catheterization laboratory itself must be well-equipped, with optimal imaging systems, resuscitative equipment, intra-aortic balloon pump (IABP) support, and must be well-stocked with a broad array of interventional equipment.
- d. The cardiac care unit nurses must be adept in hemodynamic monitoring and IABP management.
- e. The hospital administration must fully support the program and enable the fulfillment of the above institutional requirements.
- f. There must be formalized written protocols in place for immediate (within 1 h) and efficient transfer of patients to a cardiac surgical facility which are reviewed/tested on a regular (quarterly) basis.

g. Primary intervention must be performed routinely as the treatment of choice around the clock for a large proportion of patients with AMI, to ensure streamlined care paths and increased case volumes.

h. Case selection for the performance of primary angioplasty must be rigorous. Criteria for the types of lesions appropriate for primary angioplasty and for the selection for transfer for emergent aortocoronary bypass surgery are shown below:

- Avoid intervention in hemodynamically stable patients with:
 - Significant ($\geq 60\%$) stenosis of an unprotected left main (LM) coronary artery upstream from an acute occlusion in the left coronary system that might be disrupted by the angioplasty catheter
 - Extremely long or angulated infarct-related lesions with TIMI grade 3 flow
 - Infarct-related lesions with TIMI grade 3 flow in stable patients with 3-vessel disease
 - Infarct-related lesions of small or secondary vessels
 - Lesions in other than the infarct artery
- Transfer for emergent aortocoronary bypass surgery patients with:
 - High-grade residual left main or multivessel coronary disease and clinical or hemodynamic instability
 - After angioplasty or occluded vessels
 - Preferably with intraaortic balloon pump support

i. There must be an ongoing program of outcomes analysis and formalized periodic case review.

j. Institutions should participate in a 3- to 6-month period of implementation during which time development of a formalized primary PCI program is instituted that includes establishing standards, training staff,

detailed logistic development, and creation of a quality assessment and error management system.

- k. An applicant shall project a minimum of 36 Primary PCI procedures will be performed in the third 12 months of operation after initiation of service, and annually thereafter. Primary PCI volume shall be documented that the applicant transferred enough ST segment elevation AMI cases, during the most recent 12 month period preceding the date the application was filed, to maintain 36 Primary PCI cases annually. Factors that may be considered in projecting Primary PCI volume are the number of thrombolytic eligible patients per year seen in the ER (as documented through hospital pharmacy records showing the number of doses of thrombolytic therapy ordered for AMI in the ER) and/or documentation of emergency transfers to a Cardiac Surgery facility for Primary PCI.

3. Applicants proposing to provide elective Therapeutic Cardiac Catheterizations without on-site Cardiac Surgery services, in addition to Primary PCI, must meet the following requirements:

- a. The applicant must have been a provider of Primary PCI for a minimum period of two years and have met the minimum of 36 Primary PCI procedures in each of the past two years;

- b. Applicants participating in the Demonstration Pilot Project have performed the service successfully for several years. The data indicates the

participants have low incidence rates and provide a high quality service. These applicants have demonstrated need for this service through their experience in the Demonstration Pilot Project and are therefore not required to meet the requirements of Section IV, 3.c.

c. New applicants must demonstrate the need for new Therapeutic Cardiac Catheterization services on the basis of:

- (1) The need of the population to be served; and
- (2) The utilization and capacity of existing equipment in the applicant's study area.
- (3) For applicants proposing the initiation of Therapeutic Cardiac Catheterization services, the study area for Cardiac Catheterization services consists of the county of proposal and any county significantly impacted.² A significantly impacted county is a county:
 - (a) Wherein at least 25% of the residents rely on the acute care services in the county of proposal; or,

²A significantly impacted county may be a county outside West Virginia. The population projections for out of state counties must be based on authoritative sources. In addition, using authoritative sources, applicants shall document the location, description and utilization of all other cardiac catheterization laboratories in the proposed study area.

(b) A county that generates at least 10% of the applicant's acute care patient load.

For applicants performing Primary PCI and proposing the initiation of elective Therapeutic Cardiac Catheterization services, the following population based need methodology must be used:

Projected Study Area Population

(population age cohort proposed to be served by the applicant).

The applicant should include the 0-18 years population only if the applicant proposes to accept pediatric patients.

X

The most recent three-year average West Virginia Use Rate measured by the number of Therapeutic Cardiac Catheterization cases performed for inpatients.

The applicant must submit documentation of the use rates proposed.

Once the number of inpatient Therapeutic Cardiac Catheterizations are calculated, the applicant must adjust the number of cases by applying an adjustment factor for outpatient cases based on the most recent three years as reported on Worksheet 4A of the Uniform Financial Report, or conduct a survey of all facilities providing Therapeutic Cardiac Catheterization for the most recent three years.

Once the inpatient and outpatient projected Therapeutic Cardiac Catheterization cases are calculated, the applicant must subtract the number of Therapeutic Cardiac Catheterization cases performed by existing providers located in the study area, on

residents of the study area in Cardiac Catheterization laboratories in the study area to project the unmet need for Cardiac Catheterization services.

Although there may not be an existing Cardiac Catheterization laboratory in the applicant's study area, the applicant cannot realistically expect to capture 100% of the cases projected for the study area. Some patients will not be appropriate for a Therapeutic Cardiac Catheterization at a diagnostic only facility due to their health status; other patients will prefer to have a Therapeutic Cardiac Catheterization performed at a facility that has Therapeutic Cardiac Catheterization and Cardiac Surgery capabilities. Therefore, the projected number of cases for the study area must be adjusted to reflect the number of cases the applicant will capture from the study area.

If there are no existing Therapeutic Cardiac Catheterization laboratories in the applicant's study area, the applicant must adjust the projected number of cases to reflect a realistic capture rate for the applicant's facility. The applicant may use the average of the facility's most recent three-year market share of MDC-5 (Major Diagnostic Category –5, diseases and disorders of the circulatory system) discharges in its proposed study area, or the applicant may adjust the projected cases based on the average market share for Therapeutic Cardiac Catheterization cases of all Therapeutic Cardiac Catheterization providers within the state for the most recent three-year period. Documentation of the adjustment factor used must be submitted by the applicant.

If the applicant is unable to obtain reliable utilization information on Therapeutic Cardiac Catheterization laboratories located in the applicant's out-of-state study area, the

applicant shall subtract the minimum volume of 300 cases per Cardiac Catheterization laboratory.

The applicant must project 200 Therapeutic Cardiac Catheterization procedures (Primary PCI and Elective) by the end of the third year of operation.

To improve access, special consideration may be given for primary and elective PCI at facilities not within one (1) hour normal drive time from an existing facility providing primary and elective PCI; provided that the facility has performed an average of 300 Diagnostic Cardiac Catheterizations annually for the most recently completed two (2) year period.

V. REPLACEMENT CARDIAC CATHETERIZATION LABORATORIES

Applicants proposing the replacement of existing Cardiac Catheterization laboratories must demonstrate the following:

A. A facility with Dedicated Cardiac Catheterization laboratories must have performed 300 cases per laboratory during the preceding twelve-month period;

B. Non-Dedicated Cardiac Catheterization laboratories in facilities which do not have any other room capable of performing radiological arteriography must have performed 300 Cardiac Catheterization cases during the preceding twelve-month period;

or,

C. The existing laboratory can no longer be expected to function appropriately because maintenance and repair costs are excessive; parts cannot be obtained for a discontinued unit; or the age of the equipment has exceeded the AHA guidelines for useful life.

VI. EXPANSION OF CARDIAC CATHETERIZATION SERVICES BY EXISTING PROVIDERS

Existing providers of Cardiac Catheterization services proposing to add an additional Cardiac Catheterization laboratory must demonstrate the following:

A. That the applicant:

1. has performed an average of 1,250 cases per laboratory during the preceding twelve-month period; or,
2. can project, using the need methodology contained in Section III. D. of these standards, in combination with the number of procedures actually performed in the existing laboratory, a total of 1,550 cases to be performed per year by the end of the third twelve-month period after addition of the second laboratory.

B. In addition to establishing compliance with A. above, all other Cardiac Catheterization laboratories, dedicated or non-dedicated, located in the study area counties in West Virginia must have completed 625 cases in the preceding twelve-month period (or an average of 625 per laboratory in a facility with more than one laboratory).

However, if any other provider of Cardiac Catheterization services in the study area has failed to reach this threshold within four years of receiving Certificate of Need approval to initiate Cardiac Catheterization services, the presence of that provider shall not preclude the expansion of Cardiac Catheterization services by the applicant.

VII. FREESTANDING AND MOBILE CARDIAC CATHETERIZATION SERVICES

Applicants proposing the development of a Mobile Cardiac Catheterization laboratory or a Freestanding Cardiac Catheterization laboratory must demonstrate that the criteria outlined above for stationary Cardiac Catheterization laboratories will be met at each site proposed for the Mobile Cardiac Catheterization laboratory or the Freestanding Cardiac Catheterization laboratory. These services may only be provided by an acute care facility. Applicants must document that a written plan for the emergency transfer of patients is in place.

VIII. QUALITY

Applicants seeking Certificate of Need approval for Cardiac Catheterization services shall demonstrate evidence of the ability to meet all quality and safety standards applicable to this service as adopted by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the American College of Cardiology (ACC), and the American Heart Association (AHA). In addition, if the applicant is not a provider of Cardiac Surgery, specific documentation must be provided addressing the applicant's protocols for patient screening and transfers. Approved providers of Cardiac Catheterization services shall participate in and submit the required information to the ACC/National Cardiovascular Data Registry (NCDR). In addition, approved applicants must cooperate with all quality improvement programs as directed by the Authority. Approved providers shall report cardiac catheterization volumes to the Authority on a quarterly basis, unless more frequent reporting is required.

The volume projections contained in a Certificate of Need application will be compared to the actual volumes of the Cardiac Catheterization laboratory to ensure compliance with the volume requirements contained in these Standards.

IX. COST

A. The applicant shall demonstrate the cost effectiveness of any proposal for new, replacement, or additional Cardiac Catheterization laboratories by the end of the third year of operation, or identify other sources of revenue or income that will subsidize the deficit.

B. The applicant must demonstrate financial feasibility. The applicant must also demonstrate that the capital costs of the project are consistent with the current Authority rate setting methodology. The applicant must further demonstrate that the charges and costs used in projecting financial feasibility are equitable in comparison to prevailing rates for similar services in similar hospitals.

X. ACCESSIBILITY

Cardiac Catheterization services shall be reasonably accessible to all West Virginians, without regard to ability to pay.

XI. DEMONSTRATION PILOT PROJECT

Hospitals currently approved to participate in the Demonstration Pilot Project must apply for a Certificate of Need to provide Therapeutic Cardiac Catheterization services within six months of the effective date of these Standards.

These participants in the Demonstration Pilot Project may continue to provide Therapeutic Cardiac Catheterization services in accordance with the terms of their approval pending the issuance of a final decision on their Certificate of Need application.