

## CARDIAC SURGERY

### I. PREAMBLE

Establishing new standards for the treatment of one of West Virginia's most prevalent diseases demonstrates the balancing act the West Virginia Health Care Authority (Authority) strives to achieve between quality, access and cost.

The Authority's mission is to ensure that West Virginians have appropriate access to quality, affordable health care services while protecting consumers from unreasonable increases in the cost of health care arising from excessive acute care hospital rate increases and the unnecessary duplication of services.

Heart disease is the leading cause of death in West Virginia. Information from the American Heart Association, Heart Disease and Stroke Statistics – 2005 Update shows that 50 states plus the District of Columbia and Puerto Rico, West Virginia ranked 50<sup>th</sup> in the age-adjusted death rate for Total Cardiovascular Disease with 382.6 deaths per 100,000 population, and 48<sup>th</sup> in the death rate for Coronary Heart Disease with 209.7 deaths per 100,000 population.

The Authority recognizes that advances in Cardiac Surgery now make it possible for community hospitals to have successful programs. While the Authority must continue to exercise its role as the gatekeeper of service duplication, it recognizes that increased access to services would be greatly beneficial to West Virginians. The Authority is also very cognizant of the fact that in this arena, quality outcomes are highly correlated to the volume of cases.

Applicants may distinguish themselves by demonstrating broad-based community support for their provision of Cardiac Surgery, including support from referring physicians, patients and acute care facilities within their service areas. Another distinguishing characteristic is the provision of charity care, which is defined as the provision of uncompensated care to indigent people and does not include accounts written off as bad debts, contractual adjustments or third-party adjustments. While the need methodology found in Section IV of the Standards must be met as a condition precedent to approval, the Authority will examine the applications with the goal of promoting geographic access to Cardiac Surgery to all West Virginians. Finally, applicants may distinguish themselves by demonstrating their provision of community outreach and education services which are targeted to reduce the health status indicators of obesity, smoking, and sedentary lifestyle, with the goal of reducing the incidence of heart disease.

## II. DEFINITIONS

A. Cardiac Catheterization: As defined in the Cardiac Catheterization standards.

B. Cardiac Surgery: Surgery on the heart or major blood vessels of the heart including both Open and Closed Heart Surgery.

C. Cardiac Surgery Unit: A single or joint program providing Cardiac Surgery at a single site. An applicant providing Cardiac Surgery at more than one site shall consider each site a separate unit. The capacity of a Cardiac Surgery operating room is 500 cases per year, based on two cases per day for 250 days.

D. Closed Heart Surgery: A Cardiac Surgery which does not involve the use of a heart-lung bypass machine. Coded procedures that the applicant can clearly demonstrate are Closed Heart Surgery procedures may also be used. For purposes of calculating need, one Cardiac Surgery is equivalent of one case, which may be comprised of multiple procedures.

E. Joint Applicants and Joint Application: If there is an application to provide Cardiac Surgery by more than one facility, this application shall be known as a Joint Application, and the applicants as Joint Applicants. The Joint Applicant, which will be the site of the proposed unit, must provide Diagnostic Cardiac Catheterization services.

F. Open Heart Surgery: A Cardiac Surgery during which a heart-lung bypass machine is used to perform the functions of circulation during surgery. Coded procedures that the applicant can clearly demonstrate are Open Heart Surgery procedures may also be used. For purposes of calculating need, one Cardiac Surgery is the equivalent of one case, which may be comprised of multiple procedures.

### III. CURRENT INVENTORY

The Authority shall provide to each applicant a current inventory of existing Cardiac Surgery Units in the State and their utilization levels.

### IV. NEED METHODOLOGY

A. Applicants proposing to initiate a Cardiac Surgery Unit or existing providers of Cardiac Surgery proposing an additional Cardiac Surgery Unit must demonstrate:

1. That at least 1,000 Diagnostic Cardiac Catheterization cases have been performed by the applicant in the preceding 12 months. If it is a Joint Application, at least 1,000 Diagnostic Cardiac Catheterization cases must have been performed in the preceding 12 months, in total, by the Joint Applicants. In calculating the 1,000 Cardiac Catheterization cases, Joint Applicants may count

all of the Cardiac Catheterization cases which they performed in their study areas, as defined in C of this Section, if the county of the proposed Cardiac Surgery Unit is contiguous to the county of the other Joint Applicant's facility. If the counties are not contiguous, as described herein, the Joint Applicant which will be the site of the proposed Unit may count the Cardiac Catheterization cases it has performed and the Cardiac Catheterization cases performed by the other Joint Applicant in the study area, as defined in C of this Section, of the proposed Unit; or

2. That at least 1,000 Diagnostic Cardiac Catheterization cases are projected to be performed annually by 36 months after initiation of Cardiac Surgery services. In projecting Cardiac Catheterization procedures, the Joint Applicants may only include the counties in their study area as defined in C of this Section; and,
3. That using the most recent three-year average West Virginia Cardiac Surgery Use Rate by age cohort as defined by the Authority, as applied to the population of the applicant's or Joint Applicants' study area, at least 250 Cardiac Surgeries will be performed by the new Unit annually by 36 months after initiation of the services. Applicants may also submit projections based on the most recent version of the National or Southern Use

Rates by age cohorts as defined by the National Center for Health Statistics.

B. Since Cardiac Surgery is a centralized service, applicants proposing Cardiac Surgery services must also provide evidence that all existing West Virginia Cardiac Surgery Units within two hours normal driving time of the proposed Cardiac Surgery Unit have performed at least 500 Cardiac Surgeries during the preceding 12 month period and that the initiation of new Cardiac Surgery services by the applicant will not cause any West Virginia providers of Cardiac Surgery within two hours normal driving time of the proposed Cardiac Unit which are currently performing at least 500 Cardiac Surgeries annually to fall below this procedure level.

C. For applicants proposing the initiation of Cardiac Surgery services or a new Cardiac Surgery Unit, the study area for the proposal consists of the county of proposal and any county significantly impacted. The county of proposal is the county in which the proposed Cardiac Surgery Unit will be located. The study area may include counties 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 and utilization of all Cardiac Surgery Units located in the out-of-state counties of the study area as well as the out-migration of residents for Cardiac Catheterization services to out-of-state providers. A significantly impacted county is a county:

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

In the event that the study area for an individual applicant differs from that of the facility where the proposed Cardiac Surgery Unit will be located, the study area of the proposed Cardiac Surgery Unit will govern. Joint Applicants may combine their study areas if the county in which the proposed Cardiac Surgery Unit will be located is contiguous to the county of the other Joint Applicant's facility. If the counties are not contiguous, as described herein, Joint Applicants may use only the population of the counties which are shared by the Joint Applicants in their study areas and the population of the counties which comprise the study area where the Cardiac Surgery Unit will be located.

In calculating the need for Cardiac Surgery services, the adjustments for in- and out-migration must be made as follows:

The Out-migration Adjustment

The study area population must be reduced by the percentage of study area residents who seek or will seek Cardiac Catheterization services outside the study area.

For example, if the counties comprising the Cardiac Surgery study area have a population of 500,000 and 10% of the residents who seek or will seek Cardiac Catheterization services go outside the study area for treatment, then the adjusted population in the study area would be computed as follows:

Population of study area	500,000
Percentage of residents who seek or will seek Cardiac Catheterization services outside the study area	10%
Reduction in study area population for out-migration	<u>50,000</u>
Adjusted population	450,000

The above example is for illustrative purposes only. Applicants are required to compute the adjusted population on an age-cohort specific basis by applying the percentage of residents who seek or will seek Cardiac

Catheterization services outside the study area.

Subsequent to the calculation of the adjusted population, applicants must compute the number of Cardiac Surgery cases they will perform on residents of the study area by applying the use rates specified in Section IV.A.3. of these Standards to the age-cohort adjusted population. Applicants are not permitted to include the pediatric population (0-14 age cohort) in the projection of need unless they can submit substantive evidence of their ability to serve this population.

The In-migration Adjustment

It is recognized that an applicant will draw residents from outside its defined study area. Accordingly, an applicant is permitted to include residents who migrate into the applicant’s program based on the number of Diagnostic Cardiac Catheterizations that have been historically performed on residents from outside the study area. This in-migration rate must be computed using the Authority’s UB-92 data for the most recent three-year period. The average in-migration rate for these three years must be utilized.

The in-migration adjustment must be applied subsequently to the calculation of the number of Cardiac Surgery cases that will be performed on residents of the study area. For example, if the number of Cardiac Surgery cases the applicant projects it will perform, subsequent to the out-migration adjustment specified above, is 400, and the three-year average in-migration rate is 10%, the total number of Cardiac Surgery cases would be computed as follows:

Projected number of Cardiac Surgery cases from the study area	400
Percentage of total Cardiac Surgery cases from the study area (computed at 100% minus the in-migration rate)	<u>90%</u>

Total Cardiac Surgery cases	
(400 divided by 90%)	444
Total Cardiac Surgery in-migration cases	
(444 minus 400)	44
Percent of total in-migration cases	10%

D. In projecting need for Cardiac Surgeries, applicants must subtract the actual number of surgeries performed on residents of the study area by Cardiac Surgery providers in the study area.

E. Preference shall be given to Joint Applications to provide Cardiac Surgery services. Each site or Unit must demonstrate need, under IV.

F. Notwithstanding any provision of these Standards, no new Cardiac Surgery Unit, as defined in these Standards, shall be approved in a county in which a Cardiac Surgery Unit is currently located.

V. QUALITY

The applicant shall demonstrate compliance with each of the following:

A. The applicant must maintain a fully staffed and equipped Cardiac Surgery Intensive Care Unit.

B. Staffing of the proposed Cardiac Surgery Unit must meet appropriate guidelines as indicated by the American College of Cardiology (ACC), American Heart Association (AHA) and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). The applicant shall document that it will be able to recruit adequate staff necessary for the operation of a Cardiac Surgery program including, but not limited to, the recruitment of cardiologists, cardiac surgeons, cardiac anesthesiologists, nephrologists, pulmonologists, intensivists, operating room nurses and pump perfusionists. The cost of recruiting the necessary health professionals shall be included in the demonstration of financial feasibility, as required in Section VII of these Standards. The applicant shall also provide information regarding its recruitment of health professionals for the past three years.

C. Utilization review and quality assurance programs shall be maintained.

D. The applicant shall be a participant in the ACC/National Cardiovascular Data Registry (NCDR) database.

E. The applicant must be accredited by the JCAHO.

F. There shall be at least two Cardiac surgeons who perform Cardiac Surgeries at the Unit. The surgeons who perform Cardiac Surgery at the proposed Unit must each perform a minimum of 120 Cardiac Surgeries annually by 36 months after initiation of services.

VI. CONTINUUM OF CARE

Applicants proposing Cardiac Surgery services shall have in place and make available to all patients appropriate programs and personnel to provide for all levels of post Cardiac Surgery care.

VII. COST

Applicants shall demonstrate the financial feasibility of the proposed Cardiac Surgery services by presenting projections which show that revenues will equal expenses by the end of the third year of operation. Applicants must also demonstrate that the capital costs of the project are consistent with the current Authority rate setting methodology. Applicants 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, as defined by the Authority. Applicants must provide a charity care policy, which shall include its provision of uncompensated care to indigent people, and does not include accounts written off as bad debts, contractual adjustments or third-party adjustments.

## VIII. ACCESSIBILITY

Applicants proposing Cardiac Surgery services shall demonstrate the following:

A. The existence of a scheduling priority system based on patients' medical need without regard to the source of referral or payment.

B. Accessibility for the disabled in compliance with applicable state and federal laws.

C. The provision of Cardiac Surgery services 24 hours per day, seven days per week.

## IX. WITHDRAWAL OF CERTIFICATE OF NEED

The applicant's failure to perform 250 Cardiac Surgeries annually by 36 months after initiation of the services shall result in the Authority's review of the Certificate of Need. The Authority may take any action available under the law, including withdrawal of the Certificate of Need.