

## **111-2-2-.22 Specific Review Considerations for Adult Open Heart Surgery Services.**

(1) **Applicability.** A Certificate of Need will be required prior to the establishment of a new or, subject to certain stipulations, expanded adult open heart surgical service.

(2) **Definitions.**

(a) "Adult" means persons 15 years of age and over.

(b) "Authorized service" means an adult open heart surgery service that is either existing or approved. An existing service is an authorized service that has become operational, and an approved service is an authorized service that has not become operational.

(c) "Coronary Angioplasty" means a cardiac catheterization procedure to treat coronary heart disease by utilizing a catheter with a balloon, laser, laser-assisted device, rotational device, stent placement or other mechanical means to unblock an occluded coronary artery.

(d) "Expanded Service" or "Expansion" means an adult open heart surgery service that undertakes any capital renovation or construction project in and to the physical space within the hospital where the adult open heart surgery service is or will be offered, the costs of which exceed the capital expenditure threshold at that time; or that acquires a piece of diagnostic or therapeutic equipment with a value above the equipment threshold at that time which is to be utilized in the provision of open heart surgery services; or, for any service a full four (4) years or more following implementation of an approved Certificate of Need, that increases adult open heart surgery volume to a level resulting in a 25% or more increase in procedures being performed by the service over the higher annual number of procedures having been performed during the most recent prior two calendar years. Replacement or repair of existing diagnostic or therapeutic equipment utilized in the provision of such service is not an expansion for purposes of these Rules.

(e) "Official State Component Plan" means the document related to specialized cardiovascular services developed by the Department established by the Health Strategies Council, and adopted by the Board of Community Health.

(f) "Open heart surgery" means surgery performed directly on the heart or its associated veins or arteries during which a heart and lung by-pass machine (extracorporeal pump) may be used to perform the work of the heart and lungs.

(g) "Open heart surgery service" means an organized surgical program that serves inpatients of a hospital that has a suitable operating room or suite of operating rooms, equipment, staff, intensive care unit, and all support services required to perform adult open heart surgery. The adult open heart surgery service shall be located in an acute care hospital that has an authorized adult cardiac catheterization service.

(h) "Procedure" means an adult open heart surgery operation or combination of operations performed in a single session on a single patient who appears for open heart.

**(3) Standards.**

(a)1. An application for new adult open heart surgery services shall be considered by the Department only if each and all of the following conditions are met:

(i) an applicant must have operated an existing adult cardiac catheterization service which is located in an acute care hospital setting for at least three (3) years prior to the date of application; and

(ii) an applicant shall document, based on actual service data of the applicant, survey data provided to the Department and other supporting research and documentation, that the hospital's existing adult cardiac catheterization service generated a minimum of 250 or more adult open heart surgery procedures in each of the two (2) calendar years immediately prior to submittal of the application; and

(iii) an applicant shall project and, if approved, shall document that the proposed adult open heart surgery service will be performing a minimum of 300 adult open heart surgery procedures per year within three years of initiation of the service. Such projections, at a minimum, shall include consideration of patient origin data for open heart and catheterization services, the use rate of existing services, and referral data and market patterns for existing hospital services, and cardiovascular disease incidence rates and related health indicators; and

(iv) an applicant shall document that existing and approved adult open heart surgery services in the state are not predicted to be adversely impacted as a result of the establishment of the new service. Impact on an existing or approved service shall be determined to be adverse if, based on the number of cases projected to be performed by the applicant, any of the existing or approved services would have either a decrease in volume equal to or greater than ten percent (10%) of the average annual service volume in the proceeding two calendar years or a decrease of less than ten percent (10%) of the annual service volume in the proceeding two calendar years but which would result in such service falling below a minimum of 200 open heart surgical procedures annually. In the case of an approved service, service volume should be projected in accordance with the volume projections in the approved application. An existing service that has been operational for four or more years and has not performed a minimum of 200 open heart surgical procedures in at least one of the past four years shall be excluded from a determination of adverse impact.

(v) if multiple applications are joined or comparatively reviewed, the Department shall determine whether the individual impact of the establishment of each proposed service or the cumulative impact of the establishment of two or more proposed services would adversely impact an existing or approved service or any of the proposed services if established.

2. The Department may allow an exception to the need standard and adverse impact requirements in 111-2-2-.22(3)(a)1. of this paragraph to remedy an atypical barrier to

open heart surgery services based on cost, quality, financial access, or geographic accessibility. The types of atypical barriers outlined below are intended to be illustrative and not exclusive.

(i) An atypical barrier to services based on cost may include the failure of existing providers of open heart surgical services to provide services at reasonable cost, as evidenced by the providers' charges and/or reimbursement being significantly higher (one or more standard deviations from the mean) than the charges and/or reimbursement for other providers in the state.

(ii) An atypical barrier to services based on quality may include the failure of existing providers of open heart surgical services to provide services with outcomes generally in keeping with accepted clinical guidelines, peer review programs and comparable state rates for similar populations.

(iii) An atypical barrier to services based on financial access may include the repeated failure as exhibited by a documented pattern over two or more years prior to the submission of the application, of an existing provider or group of providers of open heart surgical services within the community to provide services to indigent, charity and Medicaid patients.

(b)1. An existing adult open heart surgery service seeking an expansion or expanded service due to a capital or equipment expenditure shall be approved if the applicant complies with the general considerations and policies of 111-2-2-.09 and submits an application that demonstrates the applicant's compliance with or documents a plan and agreement to comply with the provisions of 111-2-2-.22(3)(c), (d), (e), (g), (h) and (j).

2. Any existing service seeking an expansion or expanded service based on an increase in procedures pursuant to the definition in 111-2-2-.22(2)(d) may request a determination from the Department that the service is fully in compliance with the provisions of 111-2-2-.22(3)(c), (d), (e), (g), (h) and (j). The Department may issue a determination that the service is in compliance. If the Department issues such a determination, the service will not be required to apply for a certificate of need. If the Department determines that the service is not in compliance with the above referenced conditions, the service will be required to submit a Certificate of Need application. Such an application will be eligible for mandatory expedited review pursuant to Rule 111-2-2-.07(1)(l).

(c) An applicant requesting a new or expanded adult open heart surgery service shall:

1. document that the open heart surgery service shall have the capability to implement circulatory assist devices such as intra-aortic balloon assist and prolonged cardiopulmonary procedures, including at a minimum:

- (i) repair and replacement of heart valves; and
- (ii) cardiac revascularization; and
- (iii) treatment of cardiac trauma; and
- (iv) repair of congenital defects in adults; and

(v) repair of acute aortic dissection; and

2. document that the applicant has available to the open heart surgery service a full range of hospital-based diagnostic, ancillary, and support services, including the following organizational departments or services:

(i) medicine: cardiology, hematology, nephrology; and

(ii) radiology: diagnostic, nuclear medicine; and

(iii) surgery: cardiovascular, thoracic; and

(iv) pathology: anatomic, clinical, blood bank, coagulation laboratory; and

(v) anesthesiology: inhalation therapy; echocardiology in the operating room; and

(vi) neurology; and

(vii) special laboratories: cardiac catheter/angiographic; and

(viii) clinical dietary; and

(ix) cardiac surgical intensive care unit; and

(x) pacemaker therapy; and

(xi) cardiac rehabilitation services; and

(xii) renal dialysis; and

(xiii) social services.

3. document that the service shall be available for elective procedures as needed, at least eight hours per day, five days a week, and shall document the capability to rapidly mobilize surgical and medical support teams for emergency cases 24 hours per day, seven days per week, including a plan for utilizing this capability when needed to perform emergency procedures.

(d) An applicant for a new or expanded adult open heart surgery service shall:

1. submit a written plan to the Department which, when implemented, will ensure access to cardiac surgical services for all segments of the population in the documented and proposed service area of the facility and service. Such plan shall provide a detailed strategy to reach patients not currently served within the service area, ensure continuity of care for patients transferred between facilities and shall promote planning for a continuum of cardiac services within the service area; and

2. propose a heart disease prevention program to be provided by the applicant or through formal referral agreements which, when implemented, shall include:

(i) Clinical intervention for cardiac patients (any inpatient or outpatient with a principal diagnosis of ischemic heart disease). These patients are at high risk for development of

adverse cardiovascular events and the program shall provide for the following in a comprehensive, systematic way:

(I) Assessment of risk factors including lipid disorders, hypertension, diabetes, obesity, cigarette smoking, and sedentary lifestyle;

(II) Assessment of risk factors and referral for appropriate care in first-degree relatives;

(III) Assure risk management including modification of lipid disorders by diet/exercise/drugs, modification of blood pressure level by diet/exercise/drugs, control of blood glucose level by diet/exercise/drugs, dietary counseling aimed at reduced caloric and fat intake and appropriate weight management, smoking cessation, and exercise prescription. Patients should be referred to their primary care provider with documentation of treatments provided and actions recommended; and

(IV) Establishment and maintenance of systems to assist in tracking and follow-up to determine attendance at referred services and status of risk management.

(ii) Clinical intervention for non-cardiac patients (any inpatient or outpatient whose principal diagnosis is not ischemic heart disease). For these patients, the program shall encourage the following:

(I) Assessment of risk factors including, hypertension, hypercholesterolemia, smoking, obesity, sedentary lifestyle, and history of diabetes;

(II) Provision of appropriate counseling and referral for diagnostic evaluation, treatment and risk factor modification; and

(III) Establishment and maintenance of record systems to assist in documenting risk factors identified, referrals made, and other follow-up action taken.

(iii) The program shall assure access to cardiac rehabilitation services, provided either by the hospital itself or through formal referral agreements.

(iv) The program shall provide for annual support and participation in at least three professional education programs targeted to community based health professionals, related to heart disease risk assessment, disease management in clinical settings, and case finding and referral strategies.

(v) Community based heart health promotion:

(I) The program shall provide for organization of or participation in a consortium of community-based organizations to complete an assessment of heart disease risk factors in the community as well as resources available to provide programs and services. The objective of this consortium is to mobilize and coordinate resources for target populations in the community; and

(II) Organization of or participation in at least one major community-based campaign each year related to major heart disease risk factors.

3. propose a system of outcome monitoring and quality improvement and identify at least five clinical outcomes that the applicant proposes to monitor for performance on a regular basis.

(e) An applicant for a new or expanded adult open heart surgery service shall foster an environment which assures access to individuals unable to pay, regardless of payment source or circumstances, by the following:

1. providing a written policy regarding the provision of any services provided by or on behalf of the applicant to include disease prevention and intervention services outlined in 111-2-2-.22(3)(d), that such services shall be provided regardless of race, age, sex, creed, religion, disability, or patient's ability to pay, and documentation or evidence that the applicant has a service history reflecting the principles of such a policy; and

2. providing a written commitment that services for indigent and charity patients will be offered at a standard which meets or exceeds three percent of annual, adjusted gross revenues for the adult open heart surgery service, or the applicant may request that the Department allow the commitment for services to indigent and charity to patients to be applied to the entire facility;

3. providing a written commitment to accept any patient without regard to the patient's ability to pay, unless such patient is clinically inappropriate;

4. providing a written commitment to participate in the Medicaid, Peach Care and Medicare programs and to accept any Medicaid-, Peach Care- and/or Medicare-eligible patient for services unless such patient is clinically inappropriate;

5. providing a written commitment that the applicant, subject to good faith negotiations, will participate in any state health benefits insurance programs for which the service is deemed eligible; and

6. providing documentation of the past record of performance of the applicant, and any facility in Georgia owned or operated by the applicant's parent organization, of providing services to Medicare, Medicaid, and indigent and charity patients. The applicant's or its parent organization's failure to provide services at an acceptable level to Medicare, Medicaid and indigent and charity patients, and/or the failure to fulfill any previously made commitment to indigent and charity care may constitute sufficient justification to deny the application.

(f) In considering applications joined for review for new adult open heart surgery services, the Department may give favorable consideration to an applicant which historically has provided a higher annual percentage of unreimbursed services to indigent and charity patients and a higher annual percentage of services to Medicare and Medicaid patients.

(g) An applicant for a new or expanded adult open heart surgery service shall:

1. demonstrate the intent to achieve the optimal standards established by the American College of Surgeons and the Advisory Council for Cardiothoracic Surgery of the American College for evaluating the clinical and physical environments of cardiac

surgical services and covering professional qualifications and responsibilities, staffing requirements, support services, physical plant, and equipment; and

2. document the availability of; or shall present a plan for recruiting, a qualified surgeon certified by the American Board of Thoracic Surgery with special qualifications in cardiac surgery; and

3. document a plan for obtaining a sufficient number of professional and technical staff; including cardiac intensive care nurses, for the size of the adult open heart surgery program proposed and document that the operating room team necessary for an adult open heart surgical procedure shall be available, including a cardiovascular surgeon who is board certified by the American Board of Thoracic Surgery; a second physician who is a cardiovascular or thoracic surgeon or surgical resident; a board-certified anesthesiologist trained in open heart surgery; a circulating nurse or scrub nurse (RN); an operating room technician or registered nurse trained in cardiac procedures; and one or two pump technicians, with one being certified and one qualified.

(h) An applicant for a new or expanded adult open heart surgery service shall provide documentation that the hospital is fully accredited by the Joint Commission on Accreditation of Healthcare Organization (JCAHO), and also shall provide sufficient documentation that the hospital has no history of significant licensure deficiencies and no history of conditional level Medicare and/or Medicaid certification deficiencies in the past three years and has no outstanding licensure and Medicare and/or Medicaid certification deficiencies.

(i) An applicant for a new adult open heart surgery service shall demonstrate that charges and/or reimbursement rates for the service shall compare favorably with charges and/or reimbursement rates in existing adult open heart surgery services in the state when adjusted for annual inflation. When determining the accuracy of an applicant's projected charges for adult open heart surgery procedures, the Department may compare the applicant's history of charges and/or reimbursement rates for cardiac catheterization procedures and other treatments and/or interventions for disorders of the circulatory system and for open heart procedures, if applicable, with such charges and/or reimbursement rates in other similar hospitals.

(j) An applicant for a new or expanded adult open heart surgery service must agree in writing to the following conditions:

1. establishment and maintenance of a system of continuity of care and coordination of service, as evidenced by regular and ongoing planning and quality improvement sessions with community health providers and advocacy programs; and

2. participation in a data reporting, quality improvement, outcome monitoring, and peer review system within the applicant hospital as well as a national, state or multi-hospital system which benchmarks outcomes based on national norms and which shall be named in the application and which provides for peer review between and among professionals practicing in facilities and programs other than the applicant hospital;

3. development of procedures to ensure that any surgeon authorized to perform open heart surgery for the hospital shall be required to perform at least 100 procedures on annual basis across his or her various practice settings, and shall be required to accept Medicaid or Medicare payment for services without discrimination;

4. commitment that charges for services shall be reasonable and comparable to other providers in the state and the service area;

5. provision of all required data and survey information to the Department as requested; and

6. commitment to act in good faith to fulfill all provisions and commitments documented in the application for a new or expanded service.

(k) The department may revoke a Certificate of Need after notice to the holder of the certificate and a fair hearing pursuant to the Georgia Administrative Procedure Act for failure to comply with the defined scope, location, cost, service area, and person named in an application as approved by the Department and for the intentional provision of false information to the Department by an applicant in that applicant's application.

Authority O.C.G.A. Secs. 31-5A et seq., 31-6 et seq. **History.** Original Rule entitled “Specific Review Considerations for Adult Open Heart Surgery Services” adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.