STATE HEALTH PLANNING AND DEVELOPMENT AGENCY
100 NORTH UNION STREET, SUITE 870
MONTGOMERY, ALABAMA 36104

March 2, 2005

Notice

TO: Recipients of the *Alabama State Health Plan* 2004-2007

FROM: SHPDA

SUBJECT: Adjustment for Cardiac Services 410-2-3-.03

This adjustment was approved by the SHCC at the February 10, 2005 meeting. Governor Bob Riley approved this adjustment on March 1, 2005. Please substitute pages 31 through 34.

AML/pcm

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STATE HEALTH PLANNING AND DEVELOPMENT AGENCY
100 NORTH UNION STREET, SUITE 870
MONTGOMERY, ALABAMA 36104

February 22, 2005

Honorable Bob Riley, Governor
State of Alabama
State Capitol
Montgomery, Alabama 36130

Dear Governor Riley:

The Statewide Health Coordinating Council (SHCC) at the February 10, 2005 meeting adopted the attached adjustment for Madison County to the Cardiac Services section of the 2004-2007 *State Health Plan.*

You have the approval/disapproval authority for the *State Health Plan* and all amendments/adjustments thereto. I recommend your approval.

Call me at 242-4103 if you have questions about this proposed adjustment.

Sincerely,

Alva M. Lambert

Alva M. Lambert
Executive Director

Attachment

APPROVED _____
Gov. Bob Riley

Date 3/01/05

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410-2-3-.03 **Cardiac Services**

(1) Fixed-Based Cardiac Catheterization Laboratories

(a) Discussion

1. During the past four decades, an evolution in cardiac catheterization has taken place. The role of the cardiac catheterization laboratory has progressed from study of cardiac function and anatomy for purposes of diagnosis to evaluation of candidates for surgery and finally to providing catheter-based, nonsurgical interventional treatment. This progress has stimulated an increase in demand for cardiac catheterization services.

2. From about 1982 to the present, there has been an unprecedented proliferation of cardiac catheterization services, which have now been expanded to a wider group of patients and diseases. The increase in patients and laboratories has been stimulated by the development of nonsurgical catheterization laboratory-based therapeutic procedures for palliation of both stable and unstable ischemic heart disease as well as selected valvular and congenital heart diseases, arrhythmias, and other problems. Many noncardiac diagnostic and therapeutic vascular procedures are now being performed in cardiac catheterization laboratory settings, but this area is still evolving. As newer cardiac diagnostic and treatment modalities are developed, it is highly likely that the role of cardiac catheterization will continue to evolve.

3. Fixed-based cardiac catheterization services are the only acceptable method for providing cardiac catheterization services to the people in Alabama.

4. For purposes of this section, a cardiac catheterization "procedure equivalent" is defined as a unit of measure which reflects the relative average length of time one patient spends in one session in a cardiac catheterization laboratory. One procedure equivalent equals 1.5 hours utilization time.

(b) Planning Policies

1. Planning Policy

Diagnostic catheterizations shall be weighed as 1.0 equivalents, while therapeutic/interventional catheterizations (Percutaneous Transluminal Coronary Angioplasty (PTCA), directional coronary atherectomy, rotational coronary atherectomy, intracoronary stent deployment, and intracoronary fibrinolysis, cardiac valvuloplasty, and similarly complex therapeutic procedures) and pediatric catheterizations shall be weighed as 2.0 equivalents. Electrophysiology shall be weighed as 3.0 equivalents for diagnostic and 4.0 equivalents for therapeutic procedures. For multi-purpose rooms, each special procedure which is not a cardiac catheterization procedure, performed in such rooms shall be weighed as one equivalent.

2. Planning Policy - New Institutional Service

New "fixed-based" cardiac catheterization services shall be approved only if the following conditions are met:

(i) Each facility in the county has performed at least 1,000 equivalent procedures per unit for the most recent year;

(ii) An applicant for diagnostic/therapeutic cardiac catheterization must project that the proposed service shall perform a minimum of 875 equivalent procedures (60% of capacity) annually within three years of initiation of services;

(iii) An applicant for diagnostic catheterization only must project that the proposed service shall perform a minimum of 750 procedures per room per year within three years of initiation of services;

(iv) At least two physicians, licensed in Alabama, with training and experience in cardiac catheterization shall provide coverage at the proposed facility.

3. Planning Policy - Expansion of Existing Service

Expansion of an existing cardiac catheterization service shall only be approved if:

(i) If an applicant has performed 1,000 equivalent procedures per unit (80% of capacity) for each of the past two years, the facility may apply for expansion of catheterization services regardless of the utilization of other facilities in the county;

(ii) Adult and pediatric procedures may be separated for those institutions with a dedicated pediatric catheterization lab in operation on the effective date of this section.

4. Planning Policy

Pediatric cardiac catheterization laboratories shall only be located in institutions with comprehensive pediatric services, pediatric cardiac surgery services, and a tertiary pediatric intensive care unit.

5. Planning Policy

All cardiac catheterization services without open-heart surgical capability shall have written transfer agreements with an existing open-heart program located within 45 minutes by air or ground ambulance service door to door from the referring facility. Facilities performing PTCAs and other similar, complex interventional/therapeutic procedures shall have on site open-heart surgery capability. For all other facilities providing cardiac catheterizations and that do not have open-heart surgical capability, emergency procedures are the only type of interventional/therapeutic procedures that shall be provided on a regular basis. The CON Review Board may consider

recommendations/guidelines for cardiac catheterizations adopted by the American College of Cardiology (ACC). Any adoption/change in this requirement by the ACC may automatically be updated in the State Health Plan as an informational resource. Notwithstanding the foregoing, an existing hospital in Madison County with a cardiac catheterization laboratory may participate in the Atlantic Cardiovascular Patient Outcomes Research Team ("C-PORT") elective angioplasty study without having on site open-heart surgical capability.

6. Planning Policy

Applicants for new or expanded cardiac catheterization services must demonstrate that sufficient numbers of qualified medical, nursing, and technical personnel will be available to ensure that quality health care will be maintained and without detrimentally affecting staffing patterns at existing programs within the same service area.

(2) Open Heart Surgery

(a) Discussion

1. "Open heart surgery" is a descriptive term for any surgical procedure that involves opening the chest to operate on the heart. But when people talk about "open heart surgery," they are usually referring to coronary artery bypass surgery, a procedure where the surgeon uses a blood vessel from the patient's own body to "bypass" a blockage in one of the arteries supplying blood to the heart. (www.dh.org)

2. In the last forty years, open-heart surgery has emerged from operating rooms of medical centers to become a mainstay of advanced medical treatment. In the year 2000, 686,000 open-heart surgeries were performed in the United States; and while the procedure has become commonplace, it still requires uncommon skill and the most advance technology to insure successful outcome. (www.americanheart.org)

3. Highly specialized open-heart operations require very costly, highly specialized manpower, and facility resources. Thus, every effort should be made to limit duplication and unnecessary expenditures for resources related to the performance of open-heart operations, while maintaining high quality of care.

4. Based on recommendations by various professional organizations and health planning agencies, a minimum of 200 heart operations should be performed annually to maintain quality of patient care and to minimize the unnecessary duplication of health resources. In order to prevent duplication of existing resources which may not be fully utilized, the opening of new open heart surgery units should be contingent upon existing units operating, and continuing to operate, at a level of at least 350 operations per year.

5. In units that provide services to children, lower targets are indicated because of the special needs involved. In case of units that provide services to both adults and children, at least 200 open-heart operations should be performed including 75 for children.

6. In some areas, open-heart surgical teams, including surgeons and specialized technologists, are utilizing more than one institution. For these institutions, the guidelines may be applied to the combined number of open-heart operations performed by the surgical team where an adjustment is justifiable and promotes more cost-effective use of available facilities and support personnel. In such cases, in order to maintain quality care, a minimum of 75 open-heart operations in any institution is advisable.

7. Data collection and quality assessment and control activities should be part of all open-heart surgery programs.

(b) Planning Policies

1. Planning Policy

Applicants for new and expanded adult open-heart surgery facilities shall project a minimum of 200 adult open-heart operations annually, 150 of which shall be coronary artery bypass graphs (CABG), within three years after initiation of service.

2. Planning Policy

Applicants for new and expanded pediatric open-heart surgery facilities shall project a minimum of 100 pediatric open-heart operations annually within three years after initiation of service.

3. Planning Policy

There shall be no additional adult open heart units initiated unless each existing unit in the county is operating and is expected to continue to operate at a minimum of 350 adult operations per year; provided, that to insure availability and accessibility, one adult open heart unit shall be deemed needed in each county not having an open heart surgery unit in which the current population estimate (as published from time to time by the Center for Business and Economic Research, University of Alabama) exceeds 150,000 without consideration of other facilities, wherever located.

4. Planning Policy

There shall be no additional pediatric open heart units initiated unless each existing unit in the service area is operating and is expected to continue to operate at a minimum of 130 pediatric open heart operations per year.

Author: Statewide Health Coordinating Council (SHCC).
Statutory Authority: § 22-21-260(4), Code of Alabama, 1975.
History: November 22, 2004; Adjusted March 1, 2005