Form APA-3
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CERTIFICATION OF ADMINISTRATIVE RULES
FILED WITH THE LEGISLATIVE REFERENCE SERVICE
JERRY L. BASSET, DIRECTOR

(Pursuant to Code of Alabama 1975, § 41-22-6, as amended).

I certify that the attached is/are a correct copy/copies of rule/s as promulgated and adopted on the 29th day of January, 2013, and filed with the agency secretary on the 1st day of February, 2013.

AGENCY NAME: State Health Planning and Development Agency
(Statewide Health Coordinating Council)

__X__ Amendment; _____ New; _____Repeal; (Mark appropriate space)

Rule No. 410-2-3-.03 (1)(b)5

(If amended rule, give specific paragraph, subparagraphs, etc., being amended)

Rule Title: Cardiac Services

ACTION TAKEN: State whether the rule was adopted with changes from the proposal due to written or oral comments;

The rule was adopted with changes from oral comments as discussed at the January 29, 2013, Public Hearing.

NOTICE OF INTENDED ACTION PUBLISHED IN VOLUME XXXI

ISSUE NO. 2, DATED November 30, 2012.

Statutory Rulemaking Authority: Code of Alabama, 1975 §§ 22-21-260(13), (15) and -274; 22-4-8(b)(2).

(Date Filed)
(For LRS Use Only)

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FEB 0 1 2013

LEGISLATIVE REF SERVICE

Alva M. Lambert

Alva M. Lambert, Executive Director
State Health Planning and Development Agency
(Certifying Officer or his or her Deputy)

(NOTE: In accordance with § 41-22-6(b), as amended, a proposed rule is required to be certified within 90 days after completion of the notice.)

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 ("OSS") 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. Acute care hospitals providing diagnostic cardiac catheterization services may provide emergency interventional/therapeutic cardiac catheterization procedures. Notwithstanding anything in the State Health Plan to the contrary, an acute care hospital without on site open-heart surgery capability may provide elective perutaneous coronary intervention (PCI) if the following criteria are met:

1. The hospital shall maintain twenty-four (24) hour, seven (7) day a week continuous coverage by at least one interventional cardiologist and catheterization laboratory team for primary PCI treatment of ST elevation myocardial infarction;

2. The hospital shall participate in a recognized national registry for cardiac catheterizations and PCI procedures, such as the National Cardiovascular Data Registry (NCDR);

3. The hospital shall obtain informed patient consent for all elective PCI procedures, including an informed consent process in which it is clearly stated that the hospital does not offer OSS, and which clearly states that the patient may request at any time to be transferred to a hospital with OSS to undergo the PCI procedure;

4. The hospital shall conduct quarterly quality review of the elective PCI services under supervision of its serving interventional cardiologists; ~~and~~

5. The hospital shall demonstrate that applicable requirements in Planning Policy 2 (ii) of this subsection (Ala. Admin. Code 410-2-3-.03(1)(b)(2)) will be met~~.~~; and

6. Hospitals shall use their best efforts to perform a minimum of 200 PCI cases per year. Any hospital performing less than 150 cases per year after the second full year of PCI operations must agree to an independent quality review of its program by an outside interventional cardiologist who is a member of the American College of Cardiology and to report a summary of such quality review confidentially to the Executive Director of SHPDA.

The CON Review Board shall consider the most recent recommendations/guidelines for cardiac catheterizations adopted by the American College of Cardiology Foundation, the American Heart Association Task Force on Practice Guidelines, and the Society for Cardiovascular Angiography and Interventions as an informational resource in considering any CON application for elective PCI services.

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: Effective November 22, 2004; Amended: Filed February 1, 2013; effective March 8, 2013.