APA-1
11/96

TRANSMITTAL SHEET FOR NOTICE OF INTENDED ACTION

Control 410 Department or Agency State Health Planning and Development Agency (Statewide Health Coordinating Council)
Rule No. 410-2-3-.03
Rule Title: Cardiac Services
___ New X Amend ___ Repeal ___ Adopt by Reference

Would the absence of the proposed rule significantly harm or endanger the public health, welfare, or safety? NO

Is there a reasonable relationship between the state's police power and the protection of the public health, safety, or welfare? YES

Is there another, less restrictive method of regulation available that could adequately protect the public? NO

Does the proposed rule have the effect of directly or indirectly increasing the costs of any goods or services involved and, if so, to what degree? NO

Is the increase in cost, if any, more harmful to the public than the harm that might result from the absence of the proposed rule? N/A

Are all facets of the rulemaking process designed solely for the purpose of, and so they have, as their primary effect, the protection of the public? YES

* *

Does the proposed rule have an economic impact? NO

If the proposed rule has an economic impact, the proposed rule is required to be accompanied by a fiscal note prepared in accordance with subsection (f) of Section 41-22-23, Code of Alabama 1975.

* *

Certification of Authorized Official

I certify that the attached proposed rule has been proposed in full compliance with the requirements of Chapter 22, Title 41, Code of Alabama 1975, and that it conforms to all applicable filing requirements of the Administrative Procedure Division of the Legislative Reference Service.

Signature of certifying officer Alva M. Lambert

Date 11-2-12

REC'D & FILED
DATE FILED
(STAMP)
NOV 02 2012

LEGISLATIVEREFSERVICE

STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

100 NORTH UNION STREET, SUITE 870
MONTGOMERY, ALABAMA 36104

NOTICE OF INTENDED ACTION

AGENCY NAME: STATE HEALTH PLANNING AND DEVELOPMENT AGENCY
(Statewide Health Coordinating Council)

RULE NO. & TITLE: 410-2-3-.03 Cardiac Services

INTENDED ACTION:
The State Health Planning and Development Agency and the Statewide Health Coordinating Council (SHCC) propose to amend the above-styled section of the *Alabama State Health Plan.*

SUBSTANCE OF PROPOSED ACTION:
This amendment will allow acute care hospitals without on site open-heart surgery capability to provide elective percutaneous coronary intervention (PCI) if the five criteria set out in the rule are met. The amendment also requires the Certificate of Need Review Board to 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.

TIME, PLACE, MANNER OF PRESENTING VIEWS:
In response to this Proposed Rule, all interested persons are invited to submit data, views, comments and/or arguments, orally or in writing. Any and all such data, comments, arguments and/or requests to orally address the SHCC shall be made in writing on or before January 3, 2013, and shall be made to:

Nicole Horn, Executive Secretary
State Health Planning and Development Agency
P. O. Box 303025
Montgomery, Alabama 36130-3025

On January 25, 2013 at 10:00 a.m., the SHCC shall conduct a public hearing in the Old Archives Chamber, 2nd Floor, Alabama State Capitol, Montgomery, Alabama, at which time it shall consider the Proposed Rule, along with all written and oral submissions in respect to the Proposed Rule. Only those interested persons who have made timely written requests will be afforded the opportunity to speak.

Copies of the proposed changes are available for review at 100 North Union Street, RSA Union Building, Suite 870, Montgomery, Alabama. Call (334) 242-4103 or visit the office Monday through Friday from 8:00 a.m. to 5:00 p.m., excluding State holidays.

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE:
January 3, 2013

CONTACT PERSON AT AGENCY:
Nicole Horn
100 North Union Street
RSA Union, STE 870
Montgomery, AL 36104
(334) 242-4103

Alva M. Lambert, Executive Director

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.~~ 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 percutaneous 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;

2. The hospital shall participate in a recognized national registry for cardiac catheterizations and PCI procedures;

3. The hospital shall obtain informed patient consent for all elective PCI procedures;

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 of this subsection (Ala. Admin. Code r. 410-2-3-.03(1)(b)2.) will be met.

The CON Review Board ~~may~~ shall consider the most recent recommendations/guidelines for cardiac catheterizations adopted by the American College of Cardiology Foundation, ~~(ACC)~~ 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. ~~Any adoption/change in this requirement by the ACC may automatically be updated in the State Health Plan as an informational resource.~~

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: _____; effective: _____.