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-.05
Rule Title: End Stage Renal Disease 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.

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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 11/21/11

DATE FILED
(STAMP)

REC'D & FILED
NOV 21 2011
LEGISLATIVE REF SERVICE

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-.05 End Stage Renal Disease Services

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

SUBSTANCE OF PROPOSED ACTION:
To allow expansion of End Stage Renal Disease treatment center in rural areas.

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 Statewide Health Coordinating Council (SHCC) shall be made in writing on or before January 3, 2012, 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 12, 2012, at 10:00 a.m., the SHCC shall conduct a public hearing in the Sutton Conference Room, Suite 732, RSA Union Building, 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. Phone (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, 2012

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

Alva M. Lambert

Alva M. Lambert, Executive Director

410-2-3-.05 **End Stage Renal Disease Services**

(1) Discussion. Prior to the 1972 enactment of Section 299 i of Public Law 92-603, End Stage Renal Disease services were provided almost exclusively for the general population in the Jefferson County area. Financing was derived from a number of sources, some with unpredictable reliability. Since the advent of Section 299 i, and its stable source of establishment, the supply of End Stage Renal Disease services in the state has dramatically increased. The supply of these services now dictates that a specific need determination is needed to guide the future development of these units.

(a) Those who suffer with End Stage Renal Disease have inadequate function to support life. Individuals with end-stage disease must rely in kidney dialysis or peritoneal dialysis to survive. End Stage Renal Disease may be caused by a number of problems including diabetes, sickle cell disease, hypertension and congenital renal disease (polycystic kidney disease).

(b) In 1991 the Legislature declared that it was in the best interest of the state and its residents for kidney disease treatment centers to be established and operated throughout the state so that any patient needing such treatment would be able to utilize a hemodialysis unit located within a reasonable distance of their home. § 22-21-378 Code of Alabama, 1975 allows kidney disease treatment centers with ten stations or less to operate in 63 of 67 counties without Certificate of Need approval. Centers in Jefferson, Madison, Mobile and Montgomery counties are required to receive certificate of need approval for any dialysis stations.

(c) In order to further expand access to End Stage Renal Disease treatment in rural areas, any existing kidney disease treatment center located in a county that does not contain all or any part of a Class 1, 2, or 3 municipality (as such classes are defined in sections 11-40-12 and 11-40-13, Code of Alabama, 1975) may qualify to add up to six (6) stations if the existing kidney disease treatment center can demonstrate an average weekly utilization at or above the Optimal Utilization of eighty percent (80%) of Present Capacity (as such terms are defined in 410-2-3-.05(2)) for a period of ten (10) consecutive weeks within the six (6) months immediately preceding the filing of a Letter of Intent for the additional stations. Such additional stations shall be considered an exception to the need methodology set forth within 410-2-3-.05(2) and shall be considered regardless of the utilization of any other kidney disease treatment centers in the county. However, any stations granted under this provision will thereafter be included in future need methodology calculations.

1. In addition to such additional information that may be required by SHPDA, a kidney disease treatment center seeking a CON under this provision must provide the following information:

A. Demonstration of compliance with the utilization rate in paragraph (1)(c);

B. The existing kidney disease treatment center has not been granted a CON for an increase of stations under this section within the preceding twelve (12) month

period, which time begins to run upon the issuance of a license for the additional stations issued by the Alabama Department of Public Health; and

C. The kidney disease treatment center must have been licensed for at least one (1) year as an End Stage Renal Disease treatment center.

~~(c)~~(d) On June 11, 2003, the Alabama Legislature passed legislation that the Alabama Department of Public Safety provide to the Alabama Organ Center (AOC) the names of all individuals who have indicated their intent to become organ donors on their license. Approximately 1,114,000 names will be added to the Legacy Organ and Tissue Donor Registry. When a potential organ donor is referred to the AOC, that information will be checked against the registry to see if the patient is listed. The information will be presented to the patient's next of kin.

~~(d)~~ (e) Other states with registries have noted increases in donation. This is the goal for Alabama.

(2) Planning Policies

(a) The determination of need for additional hemodialysis stations will be based on the utilization of present in-center hemodialysis stations (capacity at the time of application as utilized by census at the time of application) and any anticipated increases of census.

1. In calculating the present capacity, "Isolation Stations" (stations reserved for Hepatitis-B positive patients) and stations used for home hemodialysis training will be removed from the total number of stations at the facility. No further reduction of station count will be made for down-time, transients, or back-up of home patients, since provision is made for these in the Optimal Utilization Criterion.

2. Present Capacity is defined as two shifts per day, six days per week, based on the fact that most patients require three dialysis treatments per week. Third shift ("evening dialysis") will not be considered in calculating capacity since patient demand for this shift is erratic and unpredictable.

3. Optimal Utilization is defined as 80% of present capacity, thus making provision for cost-effective use of services and orderly growth, as well as reserving some capacity for down-time, transients, and back up of home patients. Optimal capacity is, therefore, 9.6 dialysis treatments per station per week (.80 x 12 dialysis treatments/station/week = 9.6 dialysis treatments/station/week).

4. Maximum Optimal Capacity is defined as the number of patients that can receive treatment under optimal capacity on a three dialysis treatment per week schedule.

EXAMPLE:

Total Stations 20

Dialysis Treatments/Station/Week	X	12
Capacity		240 Available Dialysis Treatments/Week
Optimal Utilization	X	.80
Optimal Capacity		192 Available Dialysis Treatments/Week
Patient Usage	÷	3 Dialysis Treatments/Week
Maximum Optimal Census		64 Patients

(b) Projection of census will be submitted in a yearly fashion for the three years subsequent to the date of application. Note that much of the first year will be consumed by the application process (both state and federal), construction or renovation and licensure process. Calculations of anticipated census are to be based on:

1. Present In-Center Hepatitis-Negative Hemodialysis Patients.

(i) Other patients treated by the facility in the home settings[(Home Hemodialysis, Continuous Ambulatory Peritoneal Dialysis (CAPD), Continuous Cyclic Peritoneal Dialysis (CCPD)], will be excluded; Hepatitis-B positive patients will be excluded unless the application specifically addresses the need for Hepatitis-B positive stations;

(ii) Note that if more than one End Stage Renal Disease facility exists within the defined service area, all present dialysis stations and present patients in all End Stage Renal Disease facilities must be considered in developing a demonstration of need.

2. New End Stage Renal Disease patients projections shall be based on:

(i) The total population of the county in which the stations are to be located plus any contiguous county that does not have a dialysis center.

(ii) Incidence Rate: The definition of incidence rate is the rate at which new events occur in a population. The formula to determine incidence rate is as follows: The numerator is the number of new events occurring in a defined period; the denominator is the population at risk of experiencing the event during this period. Applicant will use the 2010 state average of 421/million/year or the sum of 749/million non-white population/year plus 270/million white population/year within the service area. In 2010 there were 2041 new patients.

(iii) Note that if more than one End Stage Renal Disease facility exists within the service area, the historical distribution of patients between the facilities will be used in determining the number of new patients who will seek services at the applying facility.

(iv) Loss Rate:

(I) Death: 16.2% of the sum of the in-center census at the start of each new year plus new patients during the year.

(II) Transplantation: 2.8% of the sum of the in-center census at the start of each new year plus new patients.

(III) Home Training: 8.0% of new patients.

I. Incidence Rate: statewide average of 2010 421/million/year, or 749/million non-white population/year plus 270/million white population/year.

II. Loss Rate:

Death: 16.2% of initial census plus new patients.

Transplant: 2.8% of initial census plus new patients.

Home Training: 8.0% of new patients.

EXAMPLE:

In-Center Census Start of Year:	100 Patients
New Patients During Year:	50/150 Patients
Less: 16.2% Death	24
Less: 2.8% Transplant	4
Less: 8.0% Home Training	412
In-Center Census, Year End	110

Note: Figures for incidence rates and loss rates were obtained from the 2010 Network 8, Inc. Annual Report http://www.esrdnetwork8.org.

3. A kidney transplant is a surgical procedure by which a healthy kidney is removed from one person and implanted in the ESRD patient. Transplantation is, ideally, a one-time procedure: if the donated kidney functions properly, the patient can live a relatively normal life. There is only one transplant center operating in Alabama. The University of Alabama Hospital located in Birmingham is one of the largest kidney transplant centers in the country with 266 transplants in 2010. The number of patients waiting for transplants is 474.

4. A free-standing licensed pediatric facility shall have the ability to make application directly to the Certificate of Need Review Board for the purpose of adding dialysis stations serving pediatric patients, provided it can clearly demonstrate that the need cannot be met by existing ESRD facilities.

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

Amended: Filed: June 30, 2006; Effective: August 4, 2006. Filed: _____; Effective:
Statistical Update November 3, 2011