

**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 21st day of November, and filed with the agency secretary on the 2nd day of December, 2014.

AGENCY NAME: Statewide Health Coordinating Council

X Amendment; _____ New; _____ Repeal; (Mark appropriate space)

Rule No. 410-2-3-.05(1)(b)

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

Rule Title: End Stage Renal Disease Services

ACTION TAKEN: State whether the rule was adopted with or without changes from the proposal due to written or oral comments;

The rule was adopted without changes and as published for comment in the Alabama Administrative Monthly.

NOTICE OF INTENDED ACTION PUBLISHED IN VOLUME XXXII,

ISSUE NO. 12, AAM, DATED September 30, 2014.

Statutory Rulemaking Authority: Code of Alabama, 1975 §§ 22-21-260(13), (15)

(Date Filed)
(For LRS Use Only)

REC'D & FILED

DEC 02 2014

LEGISLATIVE REFERENCE 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-.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. § 22-21-278 Code of Alabama, 1975 allows kidney disease treatment centers with ten stations or less to operate in 61 of 67 counties without Certificate of Need approval. Centers in Jefferson, Limestone, Madison, Mobile, Montgomery and Shelby 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) shall qualify for this exception to the need methodology set forth in 410-2-3-.05(2) 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 present in-center stations developed pursuant to a CON granted under this provision will thereafter be included in future need methodology calculations in accordance with 410-2-3-.05(2).

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 twelve (12) month time period begins to run upon the issuance of a license by the Alabama Department of Public Health for the additional stations in accordance with paragraph (1)(c); 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.

(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.

(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 ($.80 \times 12$ 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(13), (15), Code of Alabama, 1975.

History: Effective November 22, 2004

Amended: Filed: June 30, 2006; effective: August 4, 2006. Amended: Filed: January 24, 2012; effective: February 28, 2012. Amended: Filed December 2, 2014; effective: January 7, 2015.

Statistical Update November 3, 2011