



Sirote & Permutt, PC
2311 Highland Avenue South
Birmingham, AL 35205-2972

PO Box 55727
Birmingham, AL 35255-5727

June 19, 2015

VIA E-MAIL & FEDERAL EXPRESS

Alva M. Lambert
Executive Director
State Health Planning & Development Agency
100 North Union Street, Suite 870
Montgomery, AL 36130

**Re: Renal Treatment Centers - Southeast, LP d/b/a Colonel Dialysis
Non-Reviewability Determination Request**

Dear Mr. Lambert:

Our firm has the pleasure of representing Renal Treatment Centers - Southeast, LP d/b/a Colonel Dialysis ("Colonel Dialysis"), a subsidiary of DaVita Healthcare Partners Inc. Colonel Dialysis proposes to develop a new dialysis facility in Cullman, Alabama, located in Cullman County.

On behalf of Colonel Dialysis, and pursuant to Section 410-1-7-.02 of the Alabama Certificate of Need Program Rules and Regulations ("CON Rules") and Alabama Code § 22-21-260 et seq., this letter is to request ("Request") your determination that Colonel Dialysis may establish and operate a new ten (10) station dialysis facility consisting of nine (9) in-center hemodialysis stations, one (1) of which will be a hemodialysis isolation station, and one (1) home training station to be used alternately for home hemodialysis training and peritoneal dialysis home training in Cullman, Alabama, located in Cullman County, without requiring CON review ("Proposal").

The following factual and legal information is submitted for your review and consideration in support of this Request. Also, enclosed is a check in the amount of \$1000.00 for the fee required by the State Health Planning and Development Agency ("SHPDA") for this Request.

1. Facts and Analysis

1.1 Colonel Dialysis proposes to establish and operate a new ten (10) station dialysis facility consisting of nine (9) in-center hemodialysis stations, one (1) of which will be a hemodialysis isolation station, and one (1) home training station to be used alternately for home hemodialysis training and peritoneal dialysis home training in Cullman, Alabama, located in Cullman County. Colonel Dialysis intends to use its isolation station for Hepatitis B negative patients when it does not have Hepatitis B positive patients on its census or Hepatitis B positive patients being dialyzed. Such use by Colonel Dialysis will be in compliance with the enclosed letter to James E. Sanders dated October 5, 2010, as well as all other CON and Alabama Department of Public Health rules and regulations.

Lenora W. Pate
Attorney at Law
lpate@sirote.com
Tel: 205-930-5162
Fax: 205-212-3801

RECEIVED

JUN 22 2015

STATE HEALTH PLANNING
AND DEVELOPMENT AGENCY



Alva M. Lambert
June 19, 2015
Page 2

1.2 The total cost of construction is estimated to be no more than \$882,600; the total cost of equipment is estimated to be no more than \$478,705; and the total cost of first year annual operating costs is estimated to be no more than \$830,407.

2. Legal Analysis

2.1 Pursuant to Ala. Code § 22-21-278, CON approval is not required for a dialysis facility located in a Class 3, 4, 5, 6, 7, or 8 municipality, as defined by Ala. Code § 11-40-12(a), which contains no more than ten (10) freestanding hemodialysis stations. However, this exemption from CON approval does not apply to a dialysis facility located in a Class 4, 5, 6, 7, or 8 municipality if such municipality, or any part of such municipality, is located in a county in which a Class 1, 2, or 3 municipality, or any part thereof, is located.

2.2 Section 410-2-3-.05(1)(b) of the State Health Plan further states that Ala. Code § 22-21-278 allows dialysis facilities with no more than ten (10) freestanding hemodialysis stations to operate in 61 of 67 counties without CON approval. Facilities in Jefferson, Limestone, Madison, Mobile, Montgomery and Shelby counties are required to receive CON approval for any dialysis stations.

2.3 The proposed location for Colonel Dialysis is Cullman, Alabama, a Class 6 municipality,¹ located in Cullman County. Cullman County does not contain a Class 1, 2, or 3 municipality.²

3. Conclusion and Request

3.1 Pursuant to Ala. Code § 22-21-278 and Section 410-2-3-.05(1)(b) of the State Health Plan, a CON would not be required to open a ten (10) station dialysis facility consisting of nine (9) in-center hemodialysis stations, one (1) of which will be a hemodialysis isolation station, and one (1) home training station to be used alternately for home hemodialysis training and peritoneal dialysis home training in Cullman, Alabama, located in Cullman County.

3.2 Therefore, this Proposal is due to be determined as non-reviewable in accordance with the Alabama CON law, rules, and regulations.

Thank you for your prompt consideration of this Request. We look forward to receiving written confirmation from you that no further regulatory approvals are required for the Colonel Dialysis Proposal by you, SHPDA, or the CON Review Board, in accordance with the laws and regulations cited above.

¹ As defined by Ala. Code § 11-40-12(a), a Class 6 municipality is a city with a population of not less than 12,000 and not more than 24,999 inhabitants. The population of Cullman is approximately 14,775 (based on 2010 U.S. Census Bureau statistics located at <http://www.census.gov/popfinder/>).

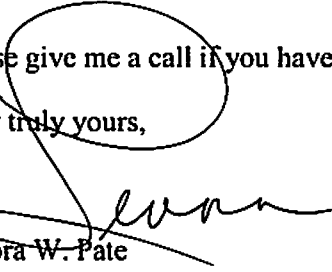
² As defined by Ala. Code § 11-40-12(a), a Class 1 municipality is a city with a population of 300,000 inhabitants or more; a Class 2 municipality is a city with a population of not less than 175,000, and not more than 299,999 inhabitants; and a Class 3 municipality is a city with a population of not less than 100,000, and not more than 174,999 inhabitants.



Alva M. Lambert
June 19, 2015
Page 3

Please give me a call if you have any questions.

Very truly yours,



Lenora W. Pate
FOR THE FIRM

LWP/ac
Enclosures

c: Nicole Horn
Gayle Ozbirn
Amy Sanford, Esq.
Sarah Talley
Kelli F. Robinson, Esq.

KELLI F. ROBINSON

ATTORNEY AT LAW

(205) 930-5158

krobinson@strote.com

SIROTE
— & —
PERMUTT
A PROFESSIONAL CORPORATION

October 5, 2010

VIA E-MAIL & U.S. MAIL

James E. Sanders
Deputy Director
State Health Planning and Development Agency
100 North Union Street, Suite 870
Montgomery, AL 36104

Re: Use of Isolation Station for Hepatitis B Negative Patients

Dear Mr. Sanders:

This letter is to follow up and confirm our conversation on Thursday, September 16, 2010, regarding the permitted authorized use of a CON-approved isolation station at an end stage renal disease ("ESRD") facility for Hepatitis B negative patients when the ESRD facility does not have Hepatitis B positive patients on its census or Hepatitis B positive patients being dialyzed.

You confirmed that an ESRD facility may use a CON-approved isolation station for Hepatitis B negative patients when the ESRD facility does not have Hepatitis B positive patients on its census or Hepatitis B positive patients being dialyzed as long as the total number of stations used at any given time did not exceed the total number of CON-approved stations.

As confirmed by the enclosed April 2, 2010, document from Carolyn Duck at the Alabama Department of Public Health ("ADPH"), if the ESRD facility does not have Hepatitis B positive patients on its census or Hepatitis B positive patients being dialyzed, then that counted isolation station may be used for Hepatitis B negative patients in the general patient treatment area as long as the ESRD facility does not have in use more than their total number of allowed stations granted on their license at one time. Accordingly, it does not matter the number of machines that are connected to the water system as long as the number of patients receiving treatment does not exceed the CON issued. This permitted authorized use of a CON-approved isolation station has been approved by ADPH, the State Health Planning and Development Agency ("SHPDA"), and the CMS Regional Office in Dallas.

Please call me if you have any questions.

Sincerely,



Kelli F. Robinson
FOR THE FIRM

DOCSBHMA1738160A1

LAW OFFICES AND MEDIATION CENTERS
2311 HIGHLAND AVENUE SOUTH BIRMINGHAM, ALABAMA 35205
POST OFFICE BOX 55727 BIRMINGHAM, ALABAMA 35255-5727
TELEPHONE | 205.930.5100 FAX | 205.930.5101 URL | <http://www.strote.com>
Birmingham | Huntsville | Mobile

James E. Sanders
October 5, 2010
Page 2

KR/lc
Enclosure

c: Lenora W. Pate, Esq.
David Geary

April 2, 2010

Purpose: To provide clarification for the use of Isolation stations in an End Stage Renal Disease Treatment and Transplant Center.

End Stage Renal Disease Treatment and Transplant Centers are facilities that are intended to treat persons suffering permanent and irreversible kidney failure. Persons who suffer from kidney failure are unable to live without receiving a form of dialysis to clean bodily toxins from their blood system.

The current state licensure rule that applies to an isolation station is as follows:

420-5-5-.02 Administration. (9) Infection Control. (e) Cross-Contamination Prevention. 4. (g) Isolation Facilities.

1. An isolation dialysis room must be provided for all Hepatitis B Antigen Positive Dialysis Patients; the room must be partitioned from treatment areas for Hepatitis B Antigen Negative Patients and provide separate facilities from toilet, handwashing, janitorial, drug storage, blood (Hematocrit and clotting time) handling and waste storage and disposal.

2. Facilities not equipped with a Hepatitis B Isolation Section as defined above may not accept for treatment any Hepatitis B Antigen Positive Patients but must complete an Agreement to transfer any Positive Patients to a facility so equipped.

There are times when ESRD centers provide their service to individuals who are Hepatitis B positive. The census of a center will fluctuate in the number of Hepatitis B positive patients they provide care to. When a center does provide care to positive patients, those patients are the only ones who can be dialyzed at that isolation station. If the center does not have Hepatitis B positive patients on its census or positive patients being dialyzed, then that counted station may be used for Hepatitis B negative patients in the general patient treatment area; as long as the ESRD center does not have in use more than their total number of allowed stations granted on their license at one time. It does not matter the number of machines that are connected to the water system as long as the patients receiving treatment does not exceed the CON issued. This has been discussed with the CMS Regional Office in Dallas and with SHPDA. Neither of these agencies have a problem with this practice.

Example: An ESRD center has a certificate of need for 16 total hemodialysis stations. The center has a separated isolation room that provides hemo treatments for a Hepatitis B positive patient; this isolation room station is included in the total 16 station count. This leaves 15 stations for use in the general patient treatment area. The center still has a certificate of need for 16 stations. The isolation room station that is not in use can be used on the general patient treatment area, as long as the center does not treat more than 16 patients at a time.

STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

100 NORTH UNION STREET, SUITE 870
MONTGOMERY, ALABAMA 36104

October 8, 2010

Kelli F. Robinson, Esquire
Sirote & Permutt
Post Office Box 55727
Birmingham, AL 35255-5727

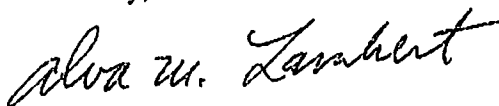
RE: Use of Isolation Station for Hepatitis B Negative Patients

Dear Ms. Robinson:

This is written in response to your letter dated October 5, 2010 to Mr. Jim Sanders in which you notified this agency that Carolyn Duck at the Alabama Department of Public Health confirms that if an ESRD facility does not have Hepatitis B positive patients on its census or Hepatitis B positive patients being dialyzed, then that counted isolation station may be used for Hepatitis B negative patients in the general patient treatment areas as long as the ESRD facility does not have in use more than their total number of allowed stations granted on their license at one time. Accordingly, it does not matter the number of machines that are connected to the water system as long as the number of patients receiving treatment does not exceed the CON issued. You report this has also been approved by CMS Regional Office in Dallas. Based on information provided, this agency also approves the use of Hepatitis B stations as outlined above.

If you have questions, please call Jim Sanders or Betty Schoenfeld at (334) 242-4103.

Sincerely,



Alva M. Lambert
Executive Director

AML:bws