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STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

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October 31, 2018

VIA E-MAIL (shpda.online@shpda.alabama.gov)

ALVA M. LAMBERT
Executive Director
State Health Planning and Development Agency
100 North Union Street, Suite 870
Montgomery, AL 36140

**Re: ISD Renal, Inc. d/b/a Heritage Dialysis
Request for Non-Reviewability Determination
Electronically Filed: October 31, 2018**

Dear Mr. Lambert:

On behalf of ISD Renal, Inc. d/b/a Heritage Dialysis (“Heritage Dialysis”) and pursuant to the Alabama Certificate of Need (“CON”) Program Rules and Regulations (“CON Rules”) § 410-1-7-.02 and § 410-1-3-.09, attached hereto as **Exhibit A** is a Request for your determination that the proposal to establish and operate a new ten (10) station dialysis facility, consisting of eight (8) in-center hemodialysis stations, one (1) of which may be used as a hemodialysis isolation station when and if needed, and two (2) home training stations which may be used alternately for home hemodialysis training and peritoneal dialysis home training in Dallas County, does **not** require a CON pursuant to Ala. Code § 22-21-278, because 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.

In accordance with CON Rule § 410-1-3-.09, a pdf text searchable copy of this Request is being submitted electronically on the 31st day of October, 2018, to shpda.online@shpda.alabama.gov; a paper original will be preserved in our files; and a fee of \$1,000.00 is being sent via overnight FedEx to SHPDA on the 31st day of October, 2018, for delivery on the next business day, November 1, 2018.

Please give me a call if you have any questions.

With kindest personal regards,

Lenora W. Pate
Tom Ansley
FOR THE FIRM

Birmingham Huntsville Mobile Pensacola



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LWP/ta

Enclosures

c: Karen McGuire
Deborah Compton
Malia Chapman

EXHIBIT A

BEFORE THE STATE HEALTH PLANNING AND DEVELOPMENT AGENCY OF THE STATE OF ALABAMA

IN THE MATTER OF:)	
)	
ISD RENAL, INC. D/B/A HERITAGE DIALYSIS)	Request for Non-Reviewability
)	Determination
)	RV-_____

REQUEST FOR NON-REVIEWABILITY DETERMINATION

On behalf of ISD Renal, Inc. d/b/a Heritage Dialysis (“Heritage Dialysis”) and pursuant to the Alabama Certificate of Need Program Rules and Regulations (“CON Rules”) § 410-1-7-.02 and § 410-1-3-.09, and Alabama Code § 22-21-260, *et.seq.*, this Request is hereby filed with the State Health Planning and Development Agency (“SHPDA”) for a determination that the Heritage Dialysis proposal, more fully described herein, to establish and operate a new ten (10) station dialysis facility, consisting of eight (8) in-center hemodialysis stations, one (1) of which may be used as a hemodialysis isolation station if and when needed, and two (2) home training stations which may be used alternately for home hemodialysis training and peritoneal dialysis home training in Dallas County, is not subject to CON Review for the reasons stated below, and that no CON is required for this Proposal (“Proposal”).

The following factual and legal information is hereby included in support of this Request, and a Heritage Dialysis check in the amount of \$1,000.00 made payable to the State Health Planning and Development Agency is being filed in accordance with CON Rule § 410-1-3-.09, simultaneously with SHPDA, as the required filing fee for this Request pursuant to CON Rule § 410-1-7-.02.

PROPOSAL

1. Facts:

1.1 ISD Renal, Inc. d/b/a Heritage Dialysis is a subsidiary of DaVita, Inc., an owner and operator of end stage renal disease facilities.

1.2 Heritage Dialysis proposes to establish and operate a new ten (10) station dialysis facility, consisting of eight (8) in-center hemodialysis stations, one (1) of which may be used as a hemodialysis isolation station if and when needed, and two (2) home training stations which may be used alternately for home hemodialysis training and peritoneal dialysis home training in Dallas County. Heritage 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 Heritage Dialysis will be in compliance with the letter to James E. Sanders dated October 5, 2010, a copy of which is attached hereto and incorporated herein as Exhibit 1, and the response letter from Alva Lambert, dated October 8, 2010, a copy of which is attached hereto and incorporated herein as Exhibit 2, as well as all other CON and Alabama Department of Public Health rules and regulations.

1.3 The total cost of construction is estimated to be \$1,238,091; the total cost of equipment is estimated to be \$750,677; and the total cost of first year annual operating costs is estimated to be \$1,530,171.

1.4 This Proposal is necessary and appropriate to provide convenient renal dialysis services to the patients located in Dallas County.

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.

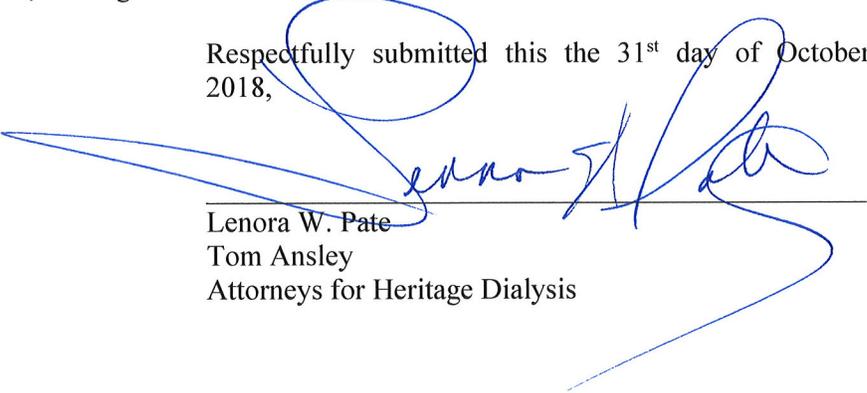
2.3 The proposed location for Heritage Dialysis is Dallas County. Dallas County does not contain a Class 1, 2, or 3 municipality.¹ There is no municipality, town, or unincorporated community in Dallas County that does not satisfy the requirements of Section 22-21-278 of the Alabama Code.

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 eight (8) in-center hemodialysis stations, one (1) of which may be used as a hemodialysis isolation station if and when needed, and two (2) home training stations which may be used alternately for home hemodialysis training and peritoneal dialysis home training in Dallas County.

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

Respectfully submitted this the 31st day of October, 2018,



Lenora W. Pate
Tom Ansley
Attorneys for Heritage Dialysis

¹ 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.

Affirmation of Requesting Party:

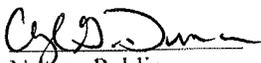
The Undersigned, being first duly sworn, hereby makes oath or affirms that she, Malia Chapman, the Regional Operations Director of ISD Renal, Inc. d/b/a Heritage Dialysis, has knowledge of the facts in this Request, and to the best of her information, knowledge and belief such facts are true and correct.



Malia Chapman

Seal

Subscribed and Sworn to before me this the 26th day of October, 2018.



Notary Public

My Commission Expires: 2.2.21.

EXHIBIT 1 TO EXHIBIT A

KELLI F. ROBINSON

ATTORNEY AT LAW
(205) 930-5158
krobinson@sirote.com

SIROTE
&
PERMUTT
A PROFESSIONAL CORPORATION

October 5, 2010

VIA E-MAIL & U.S. MAIL

James B. 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

DOCSBHM1738160\1

LAW OFFICES AND MEDIATION CENTERS
2311 HIGHLAND AVENUE SOUTH BIRMINGHAM, ALABAMA 35205
POST OFFICE BOX 57227 BIRMINGHAM, ALABAMA 35255-5727
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Birmingham | Huntsville | Mobile

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October 5, 2010
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KR/lo
Enclosure

c: Lenora W. Pate, Esq.
David Geary

DOCSBHM1738160\A

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, (a) 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 (Afamocrit 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 SERDA. 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 home 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

MAILING ADDRESS: P.O. BOX 303025, MONTGOMERY, ALABAMA 36130-3025
PHONE: (334) 242-4103 FAX: (334) 242-4113