KELLI F. ROBINSON

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

February 16, 2011



RECEIVED

FEB 1 7 2011

STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

VIA E-MAIL VIA FEDERAL EXPRESS

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

Re: AL2010-191, CON 2520-ESRD

Renal Treatment Centers - Southeast, LP d/b/a DaVita Limestone County

Request for Project Modification

Dear Mr. Sanders:

This letter is in follow up to our conversation on Monday, February 7, 2011, in which you clarified the appropriate procedure for requesting an amended Certificate of Need ("CON") where there has been a change in a facility's name since issuance of the CON.

For the State Health Planning and Development Agency ("SHPDA") to issue an amended CON reflecting a new facility name, you explained that a project modification must be filed with revised pages to the original CON Application reflecting the new facility name. You said there is no filing fee for a project modification, and you confirmed that a project modification involving only a name change would be reviewable by the Executive Director, not the full CON Review Board. You also explained that if the entity sought only a letter from SHPDA acknowledging the name change, instead of an amended CON, that only a letter request filed with SHPDA would be necessary.

On January 6, 2011, Lenora Pate filed a letter requesting that CON 2520-ESRD, which was issued to Renal Treatment Centers - Southeast, LP d/b/a DaVita Limestone County on November 29, 2010, be amended to reflect the entity's new Doing Business As (DBA) name, Limestone County Dialysis. A copy of that letter request is enclosed. In response, she received the enclosed letter from Alva Lambert dated February 2, 2011, requesting that a project modification be filed to effect a name change on CON 2520-ESRD.

As requested in Alva Lambert's February 2, 2011, letter to Lenora Pate, and in follow up to our conversation on February 7, 2011, enclosed are the revised pages to the original CON Application filed by Renal Treatment Centers - Southeast, LP d/b/a DaVita Limestone County reflecting the new DBA name, Limestone County Dialysis. Pursuant to CON Rule 410-1-10-.03, we request that Project AL2010-191 and CON 2520-ESRD be modified to reflect the name change to, Renal Treatment Centers -Southeast, LP d/b/a Limestone County Dialysis.

1763636.1

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.sirote.com

James E. Sanders February 16, 2011 Page 2

As always, we appreciate your assistance and look forward to receiving a new CON for the establishment and operation of Limestone County Dialysis reflecting this name change. If you have any questions, please give me a call immediately.

Very truly yours,

Kelli F. Robinson FOR THE FIRM

KR/Ic Enclosures

c: Lenora W. Pate, Esq. Todd Falk Carolyn Kibler

Carey B. McRae

LENORA W. PATE

ATTORNEY AT LAW (205) 930-5162 ipute@sirote.com

January 6, 2011

SIROTE ____& ___ PERMUTT

VIA E-MAIL & U.S. MAIL

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

Re:

AL2010-191; CON 2520-ESRD

Renal Treatment Centers - Southeast, LP d/b/a DaVita Limestone County

Dear Mr. Lambert:

This letter is in regards to the Certificate of Need ("CON") 2520-ESRD issued to Renal Treatment Centers - Southeast, LP d/b/a DaVita Limestone County on November 29, 2010. Since issuance of the CON, we have discovered that the facility's Doing Business As ("DBA") name has changed from "DaVita Limestone County" to "Limestone County Dialysis."

CON 2520-ESRD lists the Name of Facility as "Renal Treatment Centers - Southeast, LP d/b/a DaVita Limestone County." We would like to request that the Name of Facility on the CON be changed to "Renal Treatment Centers - Southeast, LP d/b/a Limestone County Dialysis."

As always, we appreciate your assistance and look forward to receiving an amended Certificate of Need for the establishment and operation of Limestone County Dialysis reflecting this change. If you have any questions, please give me a call immediately.

Very truly yours,

Lenora W. Pate FOR THE KIRM

LWP/ac

Kelli Robinson, Esq. c: Todd Falk Carolyn Kibler Carey B. McRae

1757469.1

LAW OFFICES AND MEDIATION CENTERS 2311 HIGHLAND AVENUC SOUTH BIRMINGHAM, ALABAMA 35205 POST OFFICE BOX 55727 BIRMINGHAM, ALABAMA 35255-5727

TELEPHONE | 205.930.5100

FAX | 205.930.5101

URL | http://www.sirote.com

Birmingham

Huntsville | Mobile



STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

100 NORTH UNION STREET, SUITE 870 MONTGOMERY, ALABAMA 36104

February 2, 2011

Lenora Pate, Esquire Sirote & Permutt, PC Post Office Box 55727 Birmingham, AL 35255-5727

> RE: AL2010-191, CON 2520-ESRD Renal Treatment Centers-Southeast, LP d/b/a DaVita Limestone County

Dear Ms. Pate:

This is in response to your letter dated January 6, 2011 regarding the facility. Doing business as ("DBA") name has changed from DaVita Limestone County to Limestone County Dialysis. The letter requested that the Certificate of Need 2520-ESRD issued November 29, 2010 for the above referenced project be changed to reflect the new name. The certificate of need was issued based upon the certificate of need application filed on May 28, 2010.

At this time it is necessary that a project modification be filed with revised pages to the original application to effect a name change on the Certificate of Need # 2520-ESRD. ADMIN. RULE 410-1-10-03 Project Modification after issuance of Certificate of Need address requirements and procedures for a project modification.

This office is processing project modification limited to name changes as they are not subject to the moratorium imposed by Executive Order Number Three issued by Governor Bentley.

Please do not hesitate to contact the Agency, if you have any questions or comments.

Sincerely,

Alva M. Lambert

ry. Lambert

AML:mde

RECEIVED FEB - 2 7/111

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

ALABAMA CERTIFICATE OF NEED APPLICATION

For Staff Use Only

INSTRUCTIONS:	Please submit an original an of this form and the appropr the State of Alabama, State Development Agency, 100 Plants Suite 870, Montgomery, Ala (Post Office Box 303025) Attached is a check in the ar Refer to Rule 410-1-7-06 of to determine the required file	iate attachments to Health Planning and North Union Street, abama 36130-3025. mount of \$19,151.00 The Certificate of Need Pr	Project # Date Rec. Rec by: rogram Rules and Regulations
PART ONE: APP	LICANT IDENTIFICATION	AND PROJECT DESCI	RIPTION
	IDENTIFICATION (Check One (Specify) End Stage Renal Disc		NURSING HOME ()
	enters — Southeast, LP d/b/a Li		
Name of Applicant (in whose name the CON will be	issued if approved)	
5200 Virginia Way	Е	Brentwood	Williamson
Address		City	County
Tannasaa	37027		(615)-870-9759
Tennessee State	Zip Code		Phone Number
Address	anization (if different from A)	City	County
State	Zip Code		Phone Number
C			
Name of Legal Own	er (if different from A or B)		
Address		City	County
State	Zip Code		Phone Number
D. Lenora W. Pate (C Name and Title of Pe	Counsel for Applicant) erson Representing Proposal and	with whom SHPDA shou	ıld communicate
Sirote & Permutt. P.C	C., 2311 Highland Ave. S.	Birmingham	<u>Jefferson</u>
Address		City	County
Alabama	35205		(205) 930-5162
State	Zip Code		Phone Number

I.	APPLIC	APPLICANT IDENTIFICATION (continued)						
	E. Type Ownership and Governing Body							
		1. 2. 3.	Individual Partnership Corporate (for profit)		DaVita, Inc. Name of Parent Corporation			
		4.	Corporate (non-profit)	<u> </u>	Name of Parent Corporation			
		5. 6.	Public Other (specify)					
	F.	Names and Titles of Governing Body Members and Owners of This Facility						
		OWNERS <u>Renal Treatment Centers – Southeast, LP d/b/a Limestone County Dialysis, a subsidiary of DaVita, Inc.</u>						
		GOVERNING BOARD MEMBERS OF RENAL TREATMENT CENTERS, INC. (General Partner of Applicant): Kent J. Thiry; Javier Rodriguez; H.W. Guy Seay; Corinna B. Polk; Thomas O. Usilton; David T. Shapiro; Chetan P. Mehta; Steven I. Grieger; Dennis Kogod; James Hilger; and Richard K. Whitney.						
		Alabar	RNING AUTHORITY OF na State Board of Health, A DiPlacido, M.D.; Todd Fall	Alabama Departm				
II.	PROJE	PROJECT DESCRIPTION						
	Project	Project/Application Type (check all that apply)						
	<u> </u>	New F Type_	acility ESRD facility		Major Medical Equipment Type			
		New S Type_	ervice		Termination of Service or Facility			
		Constr	uction/Expansion/Renovati	on	Other Capital Expenditure Type			
		Chang	e in Service					
III.	EXECU	EXECUTIVE SUMMARY OF THE PROJECT (brief description)						
		To address the demonstrated, substantial unmet need for dialysis services in Limestone County in accordance with the State Health Plan, Renal Treatment Centers—Southeast, LP d/b/a Limestone County Dialysis ("Limestone County Dialysis" or "Applicant"), a subsidiary of DaVita, Inc. ("DaVita"), proposes to establish and operate a new state-of-the-art end stage renal disease ("ESRD") facility consisting of ten (10) hemodialysis stations in Athens, Alabama, in Limestone						

A-2

in Limestone County.

County approximately five (5) miles from Athens Dialysis, an ESRD facility owned by another DaVita subsidiary and located at 15953 Athens Limestone Drive, Athens, Alabama (the "Project"). If approved, this proposed Project will address the current capacity issues at DaVita's Athens Dialysis facility, as well as the demonstrated, substantial unmet need for dialysis services

Based on the State Health Plan methodology utilizing the present in-center hemodialysis stations in Limestone County, there is a current unmet need for an additional 2 or 10 hemodialysis stations in Limestone County. Limestone County's only existing ESRD facility, DaVita's Athens Dialysis, is currently operating three (3) shifts a day on Monday, Wednesday and Friday and (2) shifts a day on Tuesday, Thursday, and Saturday, at 148% of its maximum optimal capacity as defined by the State Health Plan. Athens Dialysis currently has seven (7) patients on a waiting list who are unable to take the third shift due to transportation issues and are, therefore, forced to travel to Madison County for an earlier shift. There are also eighteen (18) of Athens Dialysis' existing patients on a waiting list to be transferred to an earlier shift at Limestone County Dialysis.

The proposed Project seeks Certificate of Need ("CON") approval to develop and operate a new ESRD facility rather than expand Athens Dialysis, a seventeen (17) hemodialysis station facility which has reached its maximum size for optimal efficiency and quality patient services. The proposed Project will not only enhance the quality of life for existing Athens Dialysis patients in need of additional scheduling options and meaningful patient choice through a convenient new centralized location within five (5) miles of Athens Dialysis, but will also address the current capacity issues and patient waiting lists at Athens Dialysis.

Limestone County Dialysis is the most appropriate applicant for this proposed Project based on the twenty (20) year history of Athens Dialysis, owned by another subsidiary of DaVita, Inc., in Limestone County as the sole provider of ESRD services to this rural, medically underserved community. DaVita enjoys an established relationship with the Limestone County community, nephrologists serving Limestone County, and ESRD patients living in Limestone County, and has excellent professional, management, and manpower capabilities to meet the current health needs and the demonstrated, substantial unmet need for ESRD services in Limestone County. Additionally, DaVita works collaboratively with both the Alabama Kidney Foundation and Athens Limestone Kidney Association, Inc. to improve ESRD care and quality of life for ESRD patients in Limestone County.

Below is the Maximum Optimal Capacity for Athens Dialysis:

Total Stations 17

Dialysis Treatments/Station/Week x 12

Capacity 204 Available Dialysis Treatments/Week

Optimal Utilization x .80

Optimal Capacity 163.2 Available Dialysis Treatments/Week

Patient Usage ÷ 3 Dialysis Treatments/Week

Maximum Optimal Census 54.4 Patients

Applying the methodology in Section 410-2-3-.05 of the State Health Plan, the Maximum Optimal Census for a 17-station facility is 54 patients. Athens Dialysis currently has 80 patients and is, therefore, operating at approximately 148% of maximum optimal capacity as defined in the State Health Plan.

¹ DaVita's Athens Dialysis, the only dialysis facility in Limestone County, currently exceeds the "Maximum Optimal Capacity" levels, as defined by the 2004-2007 State Health Plan. Present Capacity is defined in Section 410-2-3-.05(2)(a)(2) of the State Health Plan as two (2) shifts per day, six (6) days per week, based on the fact that most patients require three (3) 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. Optimal Capacity is defined in Section 410-2-3-.05(2)(a)(3) of the State Health Plan as 80% of present capacity, thus making provision for cost-effective use of services and orderly growth, as well as reserving some capacity for downtime, 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/stations/week). Maximum Optimal Capacity is defined in Section 410-2-3-.05(2)(a)(4) of the State Health Plan as the number of patients that can receive treatment under optimal capacity on a three dialysis treatment per week schedule.

PART TWO: PROJECT NARRATIVE

Note: In this part, please submit the information as an attachment. This will enhance the continuity of reading the application.

The applicant should address the items that are applicable to the project.

I. MEDICAL SERVICE AREA

A. Identify the geographic (medical service) area by county (ies) or city, if appropriate, for the facility or project. Include an 8 ½ x 11" map indicating the service area and the location of the facility.

The proposed facility will be located approximately five (5) miles from Athens Dialysis, an ESRD facility owned by another Davita, Inc. subsidiary and located at 15953 Athens Limestone Drive, Athens, Alabama. The medical service area will be Limestone County. Maps identifying the medical service area and the proposed location of the facility are attached as Exhibit "A".

B. What population group(s) will be served by the proposed project? Define age groups, location and characteristics of the population to be served.

Limestone County Dialysis will serve patients in need of dialysis therapy twelve (12) years of age and older. The population to be served by the proposal is as follows:

Medical Service Area County		Total Population	White	Non-White
	Limestone	79,702	64,870	14,832

SOURCE: All population statistics are for April 1, 2013, as determined by the Center for Business and Economic Research, The University of Alabama ("CBER").

Patients experiencing ESRD rely on long-term dialysis for survival. The incidence of ESRD in the United States is increasing at a rate of 5% per year. Over the past decade, the highest rise in incidence has been in the elderly, diabetic patients, and African Americans. Approximately 54% of ESRD patients are male, and 27% are over the age of 64. ESRD is more than four times more common among African Americans than among whites; thus, in 1997, 32% of ESRD patients were African American, even though this community represents only 12.7% of the entire U.S. population.

The incidence of ESRD and the need for dialysis treatment continues to increase as conditions that contribute to the development of ESRD increase. Obesity among Americans has risen significantly in the past several years. Furthermore, as of 2009, Alabama ranked second in the nation for highest rate of adult obesity at 31.2%, fourth in the nation for highest rate of obese and overweight adults combined at 66.5%, and sixth in the nation for highest rate of overweight and obese 10- to 17-year olds. Being obese greatly increases the risk of developing diabetes or hypertension, and these conditions are major causes of ESRD. Furthermore, the number of elderly Americans is predicted to increase sharply as the baby-boom generation begins turning 65, which will also contribute to a rise in the incidence of ESRD.

SOURCES: Sanford T. Reikes, <u>Trends in End-Stage Renal Disease</u>: <u>Epidemiology, Morbidity, and Mortality</u>, 108(1) Postgraduate Medicine 124-42 (2000); <u>F as in Fat: How Obesity Policies are Failing in America</u>, Trust for America's Health, 2009 Report, available at http://healthyamericans.org/reports/obesity2009/.

Ultimately, the incidence of ESRD in the United States is increasing at an <u>alarming rate</u>. A report by the Centers for Disease Control and Prevention (CDC) confirms that the occurrence of ESRD has risen progressively during the past 30 years. Kidney disease is the ninth leading cause of death in the U. S., and the number of new ESRD cases increased from 14,500 in 1978 to 100,359 in

<u>.</u>

2002. At the same time, the number of Americans on dialysis and with kidney transplants skyrocketed from 42,000 to 431,000. Alarmingly, CDC also reports that by 2030, the annual number of people with new onset of ESRD will exceed 450,000, and those receiving dialysis or who have had kidney transplants will top 2 million.

SOURCE: Texas Medical Association, <u>Increase the Decrease: More ESRD Patients Could Collapse Existing System</u>, available at http://www.texmed.org/Template.aspx?id=5012.

SOURCES: Center of Disease Control and Prevention, Department of Health and Human Services, U.S. Obesity Trends: 1985-2007, available at http://www.cdc.gov/nccdphp/dnpa/obesity/trend/maps/index.htm.

Sanford T. Reikes, <u>Trends in End-Stage Renal Disease</u>: <u>Epidemiology</u>, <u>Morbidity</u>, <u>and Mortality</u>, 108(1) Postgraduate Medicine 124-42 (2000); Trust for America's Health, 2009 Report, available at http://healthyamericans.org/reports/obesity2009/.

C. If medical service area is not specifically defined in the State Health Plan, explain statistical methodologies or market share studies based upon accepted demographic or statistical data available with assumptions clearly detailed. If Patient Origin Study data is used, explain whether institution or county based, etc.

Not applicable.

- D. Are there any other factors affecting access to the project?
 - (X) Geographic (X) Economic () Emergency (X) Medically Underserved

Please explain.

Medically Underserved

According to the U.S. Department of Health and Human Services, Bureau of Primary Health Care, Limestone County is currently designated as a low income Primary Medical Care Health Professional Shortage Area ("HPSA"). The HPSA system of designation is the most widely accepted measurement for determining whether an area has an adequate number of health care professionals.

Geographic

Limestone County Dialysis will be located approximately five (5) miles from Athens Dialysis, an ESRD facility owned by another DaVita, Inc. subsidiary which is currently operating at 148% of its maximum optimal capacity as defined by the State Health Plan. Therefore, the establishment and operation of Limestone County Dialysis, a new state-of-the-art ESRD facility consisting of ten (10) hemodialysis stations, would alleviate the existing demand for ESRD services by Athens Dialysis patients while allowing many patients to continue treatment in the geographical area that is most convenient for them.

Economic

Expansion of Athens Dialysis, which currently consists of seventeen (17) hemodialysis stations, is not a viable alternative to this proposed Project because of the significant need for ESRD services in the area and because Athens Dialysis has reached its maximum size for optimal efficiency and quality patient services. Thus, in light of the significant need for ESRD services in the area and the operational difficulties that can result by expanding an already-large facility, the establishment and operation of a new facility in close proximity to the existing facility is the most economical and efficient way to address the demonstrated, substantial unmet need of this area and the increasing demand of Athens Dialysis patients.

Because of the geographic and economic factors present, as well as the fact that the primary medical service area is designated as a low income Primary Medical Care HPSA, this proposed

Project will provide needed access to medical care by better serving existing and future ESRD patients and by addressing the demonstrated, substantial unmet need in the medical service area.

II. HEALTH CARE REQUIREMENTS OF THE MEDICAL SERVICE AREA

A. What are the factors (inadequacies) in the existing health care delivery system which necessitate this project?

Limestone County Dialysis will be located approximately five (5) miles from the only existing ESRD facility in Limestone County - Athens Dialysis, owned by another DaVita, Inc. subsidiary and currently operating at approximately 148% of its maximum optimal capacity as defined in the State Health Plan. Therefore, the high demand for services by existing Athens Dialysis patients and high utilization rates at Athens Dialysis, as well as the demonstrated, substantial unmet need in the medical service area, necessitates this proposed Project.

B. How will the project correct the inadequacies?

The establishment and operation of a new state-of-the-art ESRD facility consisting of ten (10) hemodialysis stations in Athens, Alabama, in Limestone County approximately five (5) miles from Athens Dialysis, an ESRD facility owned by another DaVita subsidiary and located at 15953 Athens Limestone Drive, Athens, Alabama, will correct the inadequacies in the existing system. Approval of the proposed Project will allow DaVita to address the current capacity issues at DaVita's Athens Dialysis facility, as well as the demonstrated, substantial unmet need for dialysis services in Limestone County.

Based on the State Health Plan methodology utilizing the present in-center hemodialysis stations in Limestone County, there is a current unmet need for an additional 9 or 10 hemodialysis stations in Limestone County. Limestone County's only existing ESRD facility, DaVita's Athens Dialysis, is currently operating three (3) shifts a day on Monday, Wednesday and Friday and (2) shifts a day on Tuesday, Thursday, and Saturday, at 148% of its maximum optimal capacity as defined by the State Health Plan. Athens Dialysis currently has seven (7) patients on a waiting list who are unable to take the third shift due to transportation issues and are, therefore, forced to travel to Madison County for an earlier shift. There are also eighteen (18) of Athens Dialysis' existing patients on a waiting list to be transferred to an earlier shift at Limestone County Dialysis.

The proposed Project seeks CON approval to develop and operate a new ESRD facility rather than expand Athens Dialysis, a seventeen (17) hemodialysis station facility which has reached its maximum size for optimal efficiency and quality patient services. The proposed Project will not only enhance the quality of life for existing Athens Dialysis patients in need of additional scheduling options and meaningful patient choice through a convenient new location near Athens Dialysis, but will also address the current capacity issues and patient waiting lists at Athens Dialysis.

Furthermore, because of the cost and operational efficiencies involved in this proposed Project, the proposed Project will not only correct the inadequacies present in the current system, it will do so in the most cost-effective way.

C. Why is your facility/organization the appropriate facility to provide the proposed project?

DaVita, the parent corporation of Limestone County Dialysis, is the largest independent provider of ESRD services in the United States. DaVita serves nearly 1,500 outpatient dialysis centers located in 41 states and the District of Columbia, serving approximately 100,000 patients.

Limestone County Dialysis is the most appropriate applicant for this proposed Project based on the twenty (20) year history of Athens Dialysis, owned by another subsidiary of DaVita, Inc., in Limestone County as the sole provider of ESRD services to this rural, medically underserved community. DaVita enjoys an established relationship with the Limestone County community,

The establishment of ten (10) hemodialysis stations at Limestone County Dialysis would help address this demonstrated, substantial unmet need, allowing for better and more efficient health service of the population.

E. If the application is for a specialized or limited-purpose facility or service, show the incidence of the particular health problem.

Not Applicable.

F. Describe the relationship of this project to your long-range development plans, if you have such plans.

The goal of DaVita is to meet the needs of its ESRD patients by providing quality, compassionate, cost-effective care. The establishment and operation of Limestone County Dialysis is directly in line with DaVita's mission of continuing to provide the Limestone County ESRD patient community with superior and efficient state-of-the-art service. Thus, the proposed Project is fully compatible with DaVita's overall long range plans, as well as DaVita's long range plans in Limestone County.

III. RELATIONSHIP TO EXISTING OR APPROVED SERVICES AND FACILITIES

A. Identify by name and location the existing or approved facilities or services in the medical service area similar to those proposed in this project.

There is only one (1) ESRD facility currently in Limestone County that is similar to the proposed Project: Athens Dialysis, owned by another DaVita, Inc. subsidiary and located at 15953 Athens Limestone Drive, Athens, Alabama, and currently operating at 148% of maximum optimal capacity.

B. How will the proposed project affect existing or approved services and facilities in the medical service area?

Limestone County's only existing ESRD facility, DaVita's Athens Dialysis, is currently operating three (3) shifts a day on Monday, Wednesday and Friday and (2) shifts a day on Tuesday, Thursday, and Saturday, at 148% of its maximum optimal capacity as defined by the State Health Plan. Athens Dialysis currently has seven (7) patients on a waiting list who are unable to take the third shift due to transportation issues and are, therefore, forced to travel to Madison County for an earlier shift. There are also eighteen (18) of Athens Dialysis' existing patients on a waiting list to be transferred to an earlier shift at Limestone County Dialysis.

The proposed Project seeks CON approval to develop and operate a new ESRD facility rather than expand Athens Dialysis, a seventeen (17) hemodialysis station facility which has reached its maximum size for optimal efficiency and quality patient services. The proposed Project will not only enhance the quality of life for existing Athens Dialysis patients in need of additional scheduling options and meaningful patient choice through a convenient new location near Athens Dialysis, but will also address the current capacity issues and patient waiting lists at Athens Dialysis.

⁴ Home training and isolation stations are <u>not</u> included in the State Health Plan need methodology. Ala. Admin. Code R. 410-2-3-.05(2)(a). Therefore, the number of existing stations in Limestone County used to calculate present need includes seventeen (17) hemodialysis stations at Athens Dialysis. The number of existing stations in Limestone County does not include one (1) isolation station and two (2) home training stations at Athens Dialysis.

C. Will there be a detrimental effect on existing providers of the service? Discuss methodologies and assumptions.

No, the proposed Project should have no detrimental effect on the existing provider since there is a demonstrated, substantial unmet need for 9 or 10 hemodialysis stations in Limestone County and the only existing ESRD facility in Limestone County, DaVita's Athens Dialysis, is currently operating at approximately 148% of its maximum optimal capacity as defined in the State Health Plan. This proposed Project will specifically address the unmet need for hemodialysis services at Athens Dialysis, allowing DaVita—a nationally recognized, comprehensive provider of ESRD services—to alleviate its own capacity issues and better serve its existing and future Limestone County patients.

D. Describe any coordination agreements or contractual arrangements for shared services that are pertinent to the proposed project.

Not applicable.

E. List the new or existing ancillary and/or supporting services required for this project and briefly describe their relationship to the project.

Limestone County Dialysis will provide the services required for operation of the facility through either employee or independent contractor staff. Transplantation services will be available through arrangements with the University of Alabama Hospital in Birmingham (UAB) and Vanderbilt University Medical Center in Nashville. Routine laboratory services will be provided by DaVita Labs in Florida, and stat laboratory services will be provided at Athens Limestone Hospital.

IV. POTENTIAL LESS COSTLY OR MORE EFFECTIVE ALTERNATIVES

A. What alternatives to the proposed project exist? Why was this proposal chosen?

This proposed Project was chosen because the establishment and operation of a new state-of-theart end stage renal disease ("ESRD") facility consisting of ten (10) hemodialysis stations in Athens, Alabama, in Limestone County approximately five (5) miles from Athens Dialysis, an ESRD facility owned by another DaVita subsidiary and located at 15953 Athens Limestone Drive, Athens, Alabama, by Limestone County Dialysis will enable DaVita to address the current capacity issues at DaVita's Athens Dialysis facility, as well as the demonstrated, substantial unmet need for dialysis services in Limestone County.

Based on the State Health Plan methodology utilizing the present in-center hemodialysis stations in Limestone County, there is a current unmet need for an additional 9 or 10 hemodialysis stations in Limestone County. Limestone County's only existing ESRD facility, DaVita's Athens Dialysis, is currently operating three (3) shifts a day on Monday, Wednesday and Friday and (2) shifts a day on Tuesday, Thursday, and Saturday, at 148% of its maximum optimal capacity as defined by the State Health Plan. Athens Dialysis currently has seven (7) patients on a waiting list who are unable to take the third shift due to transportation issues and are, therefore, forced to travel to Madison County for an earlier shift. There are also eighteen (18) of Athens Dialysis' existing patients on a waiting list to be transferred to an earlier shift at Limestone County Dialysis.

The proposed Project seeks CON approval to develop and operate a new ESRD facility rather than expand Athens Dialysis, a seventeen (17) hemodialysis station facility which has reached its maximum size for optimal efficiency and quality patient services. The proposed Project will not only enhance the quality of life for existing Athens Dialysis patients in need of additional scheduling options and meaningful patient choice through a convenient new centralized location within approximately five (5) miles of Athens Dialysis, but will also address the current capacity issues and patient waiting lists at Athens Dialysis.

Thus, approval of this proposed Project by the Certificate of Need Review Board will effectively meet the demonstrated, substantial unmet need of existing Athens Dialysis patients, and significantly improve accessibility to ESRD services in Limestone County and the surrounding area. Moreover, approval of this proposed Project will enable DaVita, a nationally recognized provider of unique and comprehensive ESRD services, to offer its Limestone County patients meaningful patient choice through additional scheduling options and convenient, accessible and centralized location options.

B. How will this project foster cost containment?

This proposed Project will increase efficiency via physical plant design and state-of-the-art dialysis machines and water systems. Furthermore, the existing DaVita support structure will support Limestone County Dialysis.

C. How does the proposal affect the quality of care and continuity of care for the patients involved?

The proposed Project will improve quality of care and quality of life by improving patient accessibility to ESRD services. If approved, the proposed Project will afford patients more flexibility in scheduling, making both their lives and the lives of their families easier. In addition, the same physicians serving patients at the existing Athens Dialysis will also be serving patients at Limestone County Dialysis. Therefore, the proposed Project will have a positive impact on both quality and continuity of care, as well as overall quality of life.

V. DESCRIBE COMMUNITY REACTION TO THE PROJECT (Attach endorsements if desired)

The medical and patient communities, as well as the community at large, are supportive of this proposed Project. Attached to this Application as Exhibit "B" are seven (7) letters of support, including letters from Congressman Parker Griffith; Bruce M. DiPlacido, M.D.; Todd A. Broome, M.D.; Walt Hennessee, Past 1st Vice President of the Alabama Kidney Foundation; Janice Moore, President of the Athens Limestone Kidney Association, Inc.; and DaVita staff and patients. Twenty-nine (29) existing Athens Dialysis patients have signed a letter indicating their support of this proposed Project.

VI. NON-PATIENT CARE

If appropriate, describe any non-patient care objectives of the facility, i.e., professional training programs, access by health professional schools and behavioral research projects which are designed to meet a national need.

Not applicable.

VII. MULTI-AREA PROVIDER

If the applicant holds itself as a multi-area provider, describe those factors that qualify it as such, including the percentage of admissions which resides outside the immediate health service area in which the facility is located.

Not applicable.

VIII. HEALTH MAINTENANCE ORGANIZATION

If the proposal is by or on behalf of a health maintenance organization (HMO), address the rules regarding HMOs, and show that the HMO is federally qualified.

Not applicable.

IX. ENERGY-SAVING MEASURES

Discuss as applicable the principal energy-saving measures included in this project.

This proposed Project will increase efficiency via state-of-the-art dialysis machines and water systems. If approved, the proposed Project will also include energy-saving measures, such as occupancy sensors in rooms for lighting; high efficiency heating, ventilating and air conditioning (HVAC) system; high efficiency (R30) building insulation; high efficiency double-paned insulated windows; all fluorescent lighting; programmable thermostats so HVAC set points change based on occupancy; photo cell for exterior lighting versus a time clock; insulated doors; and solar shades on exterior windows.

X. OTHER FACTORS

Describe any other factor(s) that will assist in understanding and evaluating the proposed project, including the applicable criteria found at 410-1-6 of the Alabama Certificate of Need Program Rules and Regulations which are not included elsewhere in the application.

410-1-6-.02 State Health Plan or Plans

"(1) The proposed new institutional health service shall be consistent with the appropriate state health facility and services plans effective at the time the application was received by the State Agency, which shall include the latest approved revisions of the following plans: (a) the most recent Alabama State Health Plan;"

The proposed Project is consistent with all applicable provisions of the 2004-2007 State Health Plan.

410-1-6-.05 Need for the Project

"(1) Determination of a substantially unmet public requirement for the proposed health care facility, service, or capital expenditure shall be made before approval may be granted. The need shall be consistent with orderly planning within the state and community for furnishing comprehensive health care. Such determination of need shall be made based on the merits of the proposal after giving appropriate consideration to the following:..."

The proposed Project is financially feasible and is consistent with DaVita's overall health and healthrelated plans for Limestone County. There is a demonstrated, substantial unmet public need for the proposed Project, as demonstrated by the number of patients requiring ESRD treatment compared to current accessibility.

Also, the proposal is location appropriate. Limestone County Dialysis will be located in Athens, Alabama, approximately five (5) miles from Athens Dialysis, owned by another DaVita subsidiary and currently operating at 148% of its maximum optimal capacity as defined by the State Health Plan. This location is central to Limestone County, convenient to existing Athens Dialysis patients, provides for adequate transportation accessibility including Alabama Kidney Foundation's volunteer transportation service, and allows for manpower availability. Furthermore, the proposed Project will comply with all zoning, building and environmental, and other regulatory requirements.

Based on the State Health Plan methodology utilizing the present in-center hemodialysis stations in Limestone County, there is a current unmet need for an additional 9 or 10 hemodialysis stations in Limestone County. Limestone County's only existing ESRD facility, DaVita's Athens Dialysis, is currently operating three (3) shifts a day on Monday, Wednesday and Friday and (2) shifts a day on Tuesday, Thursday, and Saturday, at 148% of its maximum optimal capacity as defined by the State Health Plan. Athens Dialysis currently has seven (7) patients on a waiting list who are unable to take the third shift due to transportation issues and are, therefore, forced to travel to Madison County for an earlier shift. There are also eighteen (18) of Athens Dialysis' existing patients on a waiting list to be transferred to an earlier shift at Limestone County Dialysis.

The proposed Project seeks CON approval to develop and operate a new ESRD facility rather than expand Athens Dialysis, a seventeen (17) hemodialysis station facility which has reached its maximum size for

life for existing Athens Dialysis patients in need of additional scheduling options and meaningful patient choice through a convenient new centralized location within approximately five (5) miles of Athens Dialysis, but will also address the current capacity issues and patient waiting lists at Athens Dialysis.

410-1-6-.07 Access to the Facility or Service

"(1) The contribution of the proposed service or facility in meeting the health related needs of traditionally medically underserved groups, (for example, low income persons, racial and ethnic minorities, women, and handicapped persons) particularly those needs identified in the appropriate state plan, will be considered. The purpose is to ensure that the medically underserved will receive equal access to care, that the project will be accessible to the whole community, and that the community needs the proposed project. For the purpose of determining the extent to which the proposed service will be accessible, the State Agency will consider: . . . (d) the extent to which the application offers a range of means by which a person will have access to the proposed services.

By providing its patients with a convenient, centralized location option and flexible scheduling, Limestone County Dialysis will offer a wide range of means by which patients can have access to ESRD services.

For more than twenty (20) years, DaVita's Athens Dialysis has been the sole provider of ESRD services to Limestone County, a rural and medically underserved community. DaVita enjoys an established relationship with the Limestone County community, nephrologists serving Limestone County, and ESRD patients living in Limestone County, and has excellent professional, management, and manpower capabilities to meet the current health needs and the demonstrated, substantial unmet need for ESRD services in Limestone County. Additionally, DaVita works collaboratively with both the Alabama Kidney Foundation and Athens Limestone Kidney Association, Inc. to improve ESRD care and quality of life for ESRD patients in Limestone County. DaVita will continue to use utilization monitoring and quality improvement processes to address unmet and undermet health needs in Limestone County, including the continued acceptance of Medicaid patients and other medically underserved patients for which ESRD services would be appropriate.

In summary, as has been addressed throughout this CON Application, this proposed Project by Limestone County Dialysis meets all applicable criteria found at Section 410-1-6 of the CON Rules and Regulations. The proposed Project shall be consistent with all applicable provisions of the 2004-2007 State Health Plan. The proposed Project is fully compatible with DaVita's overall long range development plan, as well as DaVita's long range development plan in Limestone County. The proposed Project will be the least costly, most efficient, most appropriate, and most effective means for meeting the demonstrated substantial, unmet need for ESRD services in Limestone County.

As addressed above in Section II(D) of this Application, there is a demonstrated substantially unmet public need for the proposed Project. Furthermore, the proposed Project is financially feasible; specific data supporting the demonstration of need for the proposed Project in Limestone County is reasonable, relevant and appropriate; the proposed Project has been carefully evaluated and is consistent with the overall health and health-related plans of both DaVita and the Limestone County community; the proposed Project is location appropriate with access to transportation, available manpower, and the Applicant is committed to communicating and cooperating with all planning, regulatory, and utility agencies and organizations that influence the facility's destiny; and there is a reasonable potential for the facility to meet licensure standards.

The population to be served by this proposed Project, Limestone County, has a demonstrated substantial, unmet need for ESRD services and the specific data supporting the demonstration of this need is reasonable, relevant, and appropriate. This CON Application relies on current population projections published by the Center for Business and Economic Research at the University of Alabama. Limestone County Dialysis anticipates no adverse effect of the proposed Project on the only other existing ESRD provider in Limestone County, DaVita's Athens Dialysis. The medical and patient communities, as well as the community at large, are supportive of this proposed Project.

The proposed Project will contribute in meeting the health related needs of traditionally medically underserved groups including low income persons, racial and ethnic minorities, women, and handicapped persons. The proposed facility will be accessible to the whole Limestone County community, including the medically underserved, and there is a demonstrated substantial, unmet need for ESRD services in Limestone County.

The proposed Project will be complimentary to and supportive of the existing health system. Limestone County Dialysis is the most appropriate applicant for this proposed Project based on the twenty (20) year history of Athens Dialysis, owned by another subsidiary of DaVita, Inc., in Limestone County as the sole provider of ESRD services to this rural, medically underserved community. DaVita enjoys an established relationship with the Limestone County community, nephrologists serving Limestone County, and ESRD patients living in Limestone County, and has excellent professional, management, and manpower capabilities to meet the current health needs and the demonstrated, substantial unmet need for ESRD services in Limestone County.

The proposed Project shall be designed and constructed in such a way as to maximize cost containment, protect the environment, and conserve energy. Construction costs for the leasehold improvements for this proposed Project are reasonable, relevant, and appropriate. The proposed Project will conform to local zoning ordinances and building codes and will comply will all applicable state statutes and regulations for the protection of the environment. Furthermore, the proposed Project will be developed and operated in compliance with the appropriate state licensure rules, regulations, and standards.

PART FOUR: UTILIZATION DATA AND FINANCIAL INFORMATION

This part should be completed for projects under \$500,000.00 and/or those projects for ESRD and home health. If this project is not one of the items listed above, please omit Part Four and complete Part Five. Indicate N/A for any questions not applicable.

I.	UTILIZATION		Years:	PROJECTED thru 12/2011	PROJECTED thru 12/2012
	A.	ESRD # Patients		27	<u>38</u>
		# Procedures		4729	<u>6306</u>
	B.	Home Health Agency # Patients			
		# of Visits			
	C.	New Equipment # Patients			
		# Procedures			٠
	D.	Other # Patients			
	· ·	# Procedures			

II. Percent of Gross Revenue

	Projected Percentages		
Source of Payment	2011	2012	
ALL Kids*	0	0	
Blue Cross/Blue Shield	18	18	
Champus/Tricare	0	0	
Charity Care**	3	3	
Medicaid	3	3	
Medicare	75	75	
Other commercial insurance	0	0	
Self pay	1	1	
Other	0	0	
Veterans Administration	0	0	
Workers' Compensation	0	0	
TOTAL	100 %	100 %	

Note: Refer to the Healthcare Financial Management Association (HFMA) Principles and Practices Board Statement Number 15, Section II.

^{*}ALL Kids is administered by Blue Cross/Blue Shield of Alabama.

^{**} Limestone County Dialysis is willing to provide uncompensated care in appropriate circumstances.

1. CERTIFICATION

The information contained in this application is true and correct to the best of my knowledge and belief.

RENAL TREATMENT CENTERS — SOUTHEAST, LP, D/B/A LIMESTONE COUNTY DIALYSIS ("APPLICANT")

By: Renal Treatment Centers, Inc.

Its: General Partner

Its: Regional Operations Director

DAVITA, INC.

("PARENT COMPANY")

By: Todd Falk

Its: Regional Operations Director

14 day of Feb. 2011

MY COMMISSION EXPIRES 10-08-2013

Author: Alva M. Lambert

Statutory Authority: § 22-21-267, 271, 275, Code of Alabama, 1975

History: Amended March 19, 1996 and July 25, 2002