

January 2, 2018

Ms. Martha Frisone, Chief
Ms. Jane Rhoe-Jones, Project Analyst
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, North Carolina 27603

Re: Public Written Comments, CON Project ID # L-11438-17,
Wilson County Dialysis

Dear Ms. Frisone:

Bio-Medical Applications of North Carolina, Inc. offers the following comments on the above referenced Certificate of Need application filed by Renal Treatment Centers – Mid-Atlantic, Inc.

The applicant has filed an application to relocate a total of 10 dialysis stations from two existing dialysis facilities to develop a new 10-station dialysis facility in Wilson County. The applicant has filed an application which should be denied.

1. The applicant has proposed an unreasonable growth rate for its Peritoneal Dialysis patient population. The applicant suggests that number of PD patients will increase by 50% in the first year of operations, and by 33% in the second year of operations of the facility. However, the applicant has not provided any basis for growth rates of this nature.

The assertions of the applicant that the home PD patient population would increase by 50%, or 33% is simply inconsistent with the realities of the patient population of Wilson County where the applicant's home PD patients currently reside.

As an additional consideration, consider the Required State Agency Findings for CON Project ID # P-8641-11 (Attachment 1), an application by Total Renal Care off North Carolina, LLC to add three stations to their Wallace Dialysis Center in Duplin County. On page 8 of the findings, the Project Analyst notes that the applicant "*provides no assumptions, methodology or projected utilization for home dialysis patients.*" The Agency expects the applicant to explain the basis for its projections of patients to be served. In this case, the applicant has failed to provide a basis for its projected patient population to be served, and the application should be denied.

2. The applicant has failed to appropriately identify the projected payor mix for its proposed facility. The applicant states that it has relied upon the information from DaVita operated facilities in Wilson County during the last full operating year (January 1 through December 31, 2016). The information provided in response to Section L, Criterion 13, Question 7, page 55, is clearly not consistent with the information provided by Total Renal Care, Inc., for the same two facilities, and for the same time period, as reported in CON Project ID # J-11410-17, the application for Clayton Dialysis Center. A copy of the information provided for Clayton Dialysis Center is included at Attachment 2.

Consider the following differences for the Wilson Dialysis facility:

Wilson Dialysis In-center Payor Mix, January 1 through December 31, 2016			
Payor Type	J-11410-17 ¹	L-11438-17 ²	Difference
Medicare	25.7%	25.6%	-0.1%
Medicaid	7.6%	7.5%	-0.1%
Commercial	8.8%	6.0%	-2.8%
Medicare/Commercial	25.7%	27.1%	+1.4%
Medicare/Medicaid	29.3%	31.6%	+2.3%
VA	2.9%	2.3%	-0.6%

Consider the following differences for the Forest Hills facility:

Forest Hills Dialysis In-center Payor Mix, January 1 through December 31, 2016			
Payor Type	J-11410-17	L-11438-17	Difference
Medicare	26.3%	27.1%	+0.8%
Medicaid	5.1%	7.6%	+2.5%
Commercial	8.5%	7.6%	-0.9%
Medicare/Commercial	17.8%	20.3%	+2.5%
Medicare/Medicaid	37.2%	33.9%	-3.3%
VA	5.1%	3.4%	-1.7%

The applicant has not offered any explanation for the differences in reported payor mix, for the same facilities, for the same year. The two applications were filed only two months apart. It is not reasonable to believe that historical information of this nature would change.

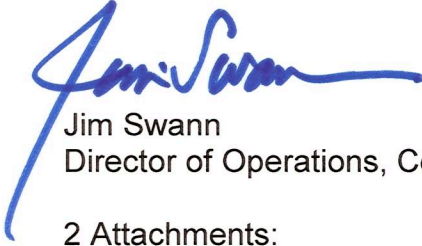
¹ CON Project ID # J-11410-17 was an application by Total Renal Care of North Carolina, LLC, filed on September 15, 2017, Total Renal Care of North Carolina, LLC is a subsidiary of DaVita Inc.

² CON Project ID # L-11438-17 is the application by Renal Treatment Centers – Mid-Atlantic, Inc. for Kenly Dialysis, filed on November 15, 2017; see page 55. Renal Treatment Centers – Mid-Atlantic, Inc. is a subsidiary of DaVita Inc.

Summary: The applicant has provided an application which should not be approved. The applicant has provided unreasonable growth estimates for its projected PD patient population (Criterion 3). Further the applicant has provided unreliable information with regard to its historical payor mix; since the historical payor mix is the foundation for the projected payor mix, and because that historical payor mix is unreliable, the projected payor mix must then be unreliable (Criterion 13). To the extent that the projections of patients to be served, and the projected payor mix are unreliable, then the applicant must be found non-conforming to those criteria and Criterion 4. An application which is not conforming to all applicable statutory review criteria can not be deemed to be the best alternative. Therefore the application must be denied.

If you have any questions please contact me at 910-568-3041, or email jim.swann@fmc-na.com.

Sincerely,



Jim Swann
Director of Operations, Certificate of Need

2 Attachments:

- 1) Extract from RSAF, CON Project ID # P-8641-11, TRC Wallace Dialysis Center,
- 2) Extracts from CON Project ID # J-11410-17, Clayton Dialysis

Attachment 1

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: July 8, 2011
PROJECT ANALYST: Jane Rhoe-Jones
TEAM LEADER: Angie Matthes

PROJECT I.D. NUMBER: P-8641-11 / Total Renal Care of North Carolina, LLC d/b/a Wallace Dialysis Center / Add three stations for a total of 15 stations upon project completion / Duplin County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

NC

Total Renal Care (TRC) of North Carolina, LLC d/b/a Wallace Dialysis Center, operates a 12-station dialysis facility at 5650 S. North Carolina Highway 41, Wallace, North Carolina. The applicant proposes to add three dialysis stations for a total of 15 stations at Wallace Dialysis Center upon completion of this project.

The 2011 State Medical Facilities Plan (2011 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the revised January 2011 Semiannual Dialysis Report (SDR), the county need methodology shows there is no need for an additional facility in Duplin County. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology, because the utilization rate reported for Wallace Dialysis Center in the January 2011 SDR is 3.92 patients per station. This utilization rate was calculated based on 47 in-center dialysis patients and 12 certified dialysis stations as of June 30, 2010 (47 patients / 12 stations = 3.92 patients per station). Therefore, application of the facility need methodology indicates additional stations are needed for this facility, as illustrated in the following table.

The average number of patients per station per week will exceed 3.2 patients per station per week as required by 10A NCAC 14C .2203(b). The number of in-center patients that the applicant projects to be served is based on reasonable and supported assumptions regarding future growth. However, the floor plan provided in Exhibit 18 shows additional space, two stations for “PD/HHD Training.”

The applicant states in Section II, page 15: “*The Wallace Dialysis Center provides in-center hemodialysis treatments to chronic End Stage Renal Disease Patients who require outpatient dialysis. The facility has an isolation area to provide dialysis treatments to patients who require isolation. The facility provides full support for patients receiving hemodialysis services. This support includes social services, dietary services, patient education, emergency care, diagnostic services and transplant evaluation.*”

Home training services are provided by Southeastern Dialysis Center-Wilmington. See Exhibit 8. [Emphasis in original.]

In Section IV.3, page 22, the applicant states, “*SEDC-Wilmington provides home training for patients living in Duplin County under an agreement with Wallace Dialysis Center.*” Also in Section V.2(d), page 25 regarding accessible follow-up for patients dialyzing at home, the applicant states, “*SEDC-Wilmington provides protocols and routines for patient follow-up.*”

The applicant provides no assumptions, methodology or projected utilization for home dialysis patients. The applicant does not provide any discussion regarding the need to add space for home dialysis training. Moreover, in Section V, page 24, the applicant states that home dialysis training will be provided by SEDC-Wilmington. The applicant does not demonstrate why additional space for home dialysis training is needed.

In summary, the applicant adequately identifies the population to be served and demonstrates the need for the three additional stations based on the population it proposes to serve. However, the applicant does not adequately demonstrate the need to add two home dialysis training stations. Therefore, the application is not conforming with this criterion.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

The applicant is not proposing to reduce or eliminate a service.

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

Attachment 2

TOTAL RENAL CARE OF NORTH CAROLINA, LLC

D/B/A

CLAYTON DIALYSIS

CERTIFICATE OF NEED APPLICATION

SEPTEMBER 15, 2017

FOR THE FACILITY TO BE LOCATED AT

**2196 HWY 42
CLAYTON, NORTH CAROLINA 27520**

JOHNSTON COUNTY

Answer Questions 1 through 4 below for **each** applicant, adding more lines, as necessary.

Applicant includes any person, as defined in G.S. 131E-176(19)*, who will:

- (a) Incur an obligation for a capital expenditure to develop or expand the dialysis facility, including acquisition of dialysis equipment; or
- (b) Offer dialysis services.

* G.S. 131E-176(19) "Person" means an individual, a trust or estate, a partnership, a corporation, including associations, joint stock companies, and insurance companies; the State, or a political subdivision or agency or instrumentality of the State.

1. Legal name of the applicant:

Total Renal Care of North Carolina, LLC d/b/a Clayton Dialysis

(Name)

91-1868873

(Federal Taxpayer ID #)

2. Document that the applicant is an existing legal entity.
(Example: Place documentation in Exhibit A, labeled Ex A-2)

See Exhibit A-2

If the applicant is not an existing legal entity, explain.

3. Address of the applicant:

2000 16th Street

(Number & Street)

Denver CO 80202

(City) (State) (Zip)

4. Name of parent company (if applicable):

DaVita Inc.

5. Contact person: Person to whom all correspondence and questions regarding this application shall be directed.

Bill Hyland Director of Healthcare Planning

(Name) (Title)

2321 West Morehead Street

(Number & Street)

Charlotte NC 28208 704-577-2853

(City) (State) (Zip) (Telephone Number)

bill.hyland@davita.com

(Email Address)

(b) Describe the current status of each complaint.

Not applicable.

For Existing Facilities and Relocation of Dialysis Stations

7. If expanding an existing facility or relocating dialysis stations from an existing facility to a new facility, complete the following table for the existing facility gaining stations or each facility that will be losing stations. If more than one facility will be losing stations, complete a separate table for each facility.

Last Full Operating Year
Historical Payor Mix – Wilson Dialysis
From: 1/1/2016 To: 12/31/2016

Payor Type	Percent of Total Patients	Percent of In-center Patients	Percent of HH Patients	Percent of PD Patients
Private Pay	0.0%	0.0%	0.0%	0.0%
Medicare	25.3%	25.7%	14.3%	29.7%
Medicaid	6.1%	7.6%	0.0%	2.7%
Commercial Insurance	10.0%	8.8%	9.5%	16.2%
Medicare / Commercial	28.0%	25.7%	42.9%	29.7%
Medicare / Medicaid	27.1%	29.3%	23.8%	19.0%
VA	3.5%	2.9%	9.5	2.7%
Other (specify)	0.0%	0.0%	0.0%	0.0%
Total	100%	100%	100%	100%

Last Full Operating Year
Historical Payor Mix – Forest Hills Dialysis
From: 1/1/2016 To: 12/31/2016

Payor Type	Percent of Total Patients	Percent of In-center Patients	Percent of HH Patients	Percent of PD Patients
Private Pay	0.0%	0.0%	0.0%	0.0%
Medicare	26.3%	26.3%	0.0%	0.0%
Medicaid	5.1%	5.1%	0.0%	0.0%
Commercial Insurance	8.5%	8.5%	0.0%	0.0%
Medicare / Commercial	17.8%	17.8%	0.0%	0.0%
Medicare / Medicaid	37.2%	37.2%	0.0%	0.0%
VA	5.1%	5.1%	0.0%	0.0%
Other (specify)	0.0%	0.0%	0.0%	0.0%
Total	100%	100%	100%	100%