

March 2, 2020

Mr. Mike McKillip, Project Analyst  
Ms. Fatima Wilson, Team Leader  
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 # J-11847-20, Downtown Raleigh Dialysis

Dear Mr. McKillip and Ms. Wilson:

The following comments are offered on behalf of Bio-Medical Applications of North Carolina, Inc., for the above referenced Certificate of Need application filed by Total Renal Care of North Carolina, LLC.

The applicant has filed an application which must be denied for myriad reasons.

**“CRITERION (3)”**: - G.S. 131E-183(a)(3) and G.S. 131E-183(b)

**Criterion (3)** - *“The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.”*

In-center discussion:

The applicant has identified a population which will not be well served by the proposed facility. The applicant includes letters of support from 31 patients residing in Wake County. A review of the letters indicates that 19 of 31 letters, 61% of the patients, reside further away from the facility than to either Oak City Dialysis or Wake Forest Dialysis.

DaVita has indicated the new location *“[I]n order to make the travel to dialysis...**more convenient** it was determined that DaVita needs to provide a dialysis facility near the central part of Wake County.”*<sup>1</sup> [emphasis added].

- The closest point of 27614 to the Poole Road location is 8.67 miles away.

---

<sup>1</sup> Application, page 23, first full paragraph.

- The entirety of 27614 is within 8.67 miles of the Wake Forest facility.
- The closest point of 27616 to the Poole Road location is 4.14 miles away.
- Nearly the entirety of 27616 is within 4.14 miles of the Oak City facility; areas of 27616 not within this 4.14 mile radius are east of the Oak City facility and a greater distance from the proposed location.

Traveling further for dialysis is not going to be more convenient or provide better access to care. It is well known within the dialysis community that patients generally prefer to receive dialysis at a facility closest to their residence. It is not reasonable to assume that a patient will drive further for dialysis, especially when the patient would have to bypass another facility which is operated by the same provider with the same physician coverage.

There is nothing in the DaVita application to suggest that the location on Poole Road is more convenient, or will provide better access to care for the 19 patients residing in these two zip codes (27614 and 27616). The applicant has provided no information to support the assumption/assertion that patients will actually travel further for dialysis care at the proposed new location.

It is incumbent upon the applicant to provide reasonable and credible projections of the patient population to be served. In this case, it simply is unreasonable to expect that dialysis patients will travel further for dialysis care.

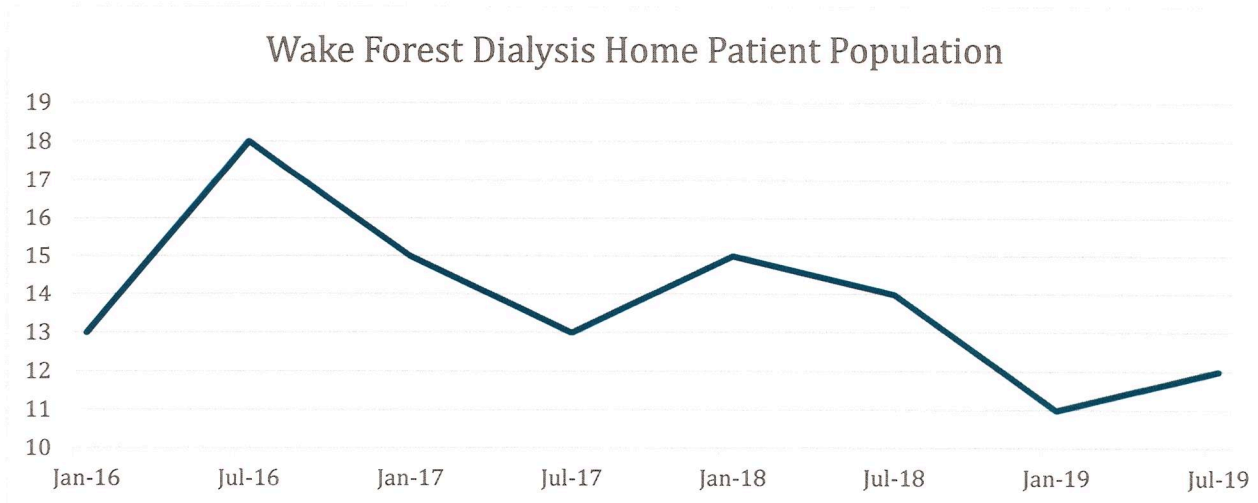
Home discussion:

In addition to the unreasonable projections for the in-center patient population, the applicant has also provided unreasonable, an unsupported projections of the home dialysis patient population to be served by the facility. The applicant provides a letter of support from one patient, and then offers the following assumption on page 22 of the application:

*“It is reasonable to assume that the Downtown Raleigh Dialysis home-training program will grow at a rate of at least one patient per year during the period of growth.”*

The applicant has not provided any assumptions regarding growth of the home patient population. Further, an assumption of one new patient each year stands in stark contrast to the realities of the applicant’s recent experience with home therapies at the Wake Forest Dialysis facility. Wake Forest Dialysis is the source for the 10 stations projected for relocation.

The following chart depicts the overall decline in the home patient population of Wake Forest Dialysis, as reported in the indicated SDR/Patient Origin Report.



In the January 2016 SDR, Wake Forest Dialysis had 13 home patients. In the 2020 SMFP, Wake Forest Dialysis reported a census of 12 home patients. Thus, the Wake Forest Dialysis track record directly contradicts the assumption of the applicant. DaVita has not been increasing their home patient population. Their home patient population has experienced a net decline of one patient over a three and one half year period.

It is not reasonable to project one new home patient each year, and the CON Agency should reject this assumption.

The applicant fails to satisfy the second prong of CON Review Criterion 3.

*“...the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, **handicapped persons**, the elderly, and other underserved groups are likely to have access to the services proposed.”*

DaVita has not projected any handicapped persons to be in the facility. The US Census Bureau reports under the heading of “Health”, “With a disability, under age 65 years, percent, 2013-2017”. The US Census Bureau includes this definition on its website:

**Definition**

*In an attempt to capture a variety of characteristics that encompass the definition of disability, the ACS identifies serious difficulty with four basic areas of functioning – hearing, vision, cognition, and ambulation. These functional limitations are supplemented by questions about difficulties with selected activities from the Katz Activities of Daily Living (ADL) and Lawton Instrumental Activities of Daily Living (IADL) scales, namely difficulty bathing and dressing, and difficulty performing errands such as shopping. Overall, the ACS attempts to capture six aspects of disability: (hearing, vision, cognitive, ambulatory, self-care, and independent living); which can be used together to create an overall disability measure, or independently to identify populations with specific disability types. For the complete definition, go to [ACS subject definitions "Disability Status."](#)*

The US Census Bureau reports that 5.8% of the Wake County population under the age of 65 has a disability as defined above. These persons would be considered as handicapped.

Taken as a whole, the Applicant has provided an application which fails to conform to Criterion 3. The projections of patients to be served include a patient population which does not reside proximate to the proposed location of the new facility, and does reside closer to other facilities operated by the applicant. Further, the applicant has grossly exaggerated growth rate for its home patient population.

**“CRITERION (4)”** - G.S. 131E-183(a)(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.”*

The applicant has proposed to develop a facility which is not central to the overwhelming majority of patients projected to transfer their care. It is not reasonable to suggest this location is more convenient for the projected patient population identified by the applicant.

The applicant suggests in part that the new facility is necessary in order to avoid a third shift as the only option for patients choosing dialysis with DaVita. However, the applicant has provided no reason it could not relocate stations to the Oak City dialysis facility.

The applicant suggests it needs to develop the new facility because Oak City does not have a Need Determination in the 2020 plan, and because Oak City will not be eligible to add stations until the 2021 SMFP is published. This is not accurate.

The applicant could have applied to relocate stations from its Wake Forest facility to the Oak City facility as opposed to the instant proposal. Nothing prevents the applicant from applying to relocate stations to the new facility. It is a practice that has been accomplished multiple times by both DaVita and Fresenius.

When DaVita filed its application to develop the Oak City facility, CON Project ID # J-11131-16, the application included the floor plan at Attachment 3. This floor plan includes capacity for six additional stations, without construction. Clearly, the applicant could have applied to relocate stations to the Oak City facility, as opposed to developing a new facility at a significantly higher capital cost.

Patients choosing dialysis with DaVita are not going to be forced to a third shift. The applicant has a total of 32 CON approved stations (10 stations at Oak City, and 22 stations at Wake Forest Dialysis). Application of the Wake County Five Year Average Annual Change Rate of 3.6% would produce a census of only 105 patients at DaVita facilities. This equates to a utilization rate of only 3.28 patients per station. The following calculations are used to arrive at this projected utilization.

Assumptions:

- A. Oak City has a census of 20 patients as of December 31, 2019.
- B. Wake Forest has a census of 80 patients as of December 31, 2019.
- C. For purposes of this calculation, BMA has relied upon the applicant's discussion at Criterion 3a (of the application). The applicant reports that of the 80 patients at Wake Forest Dialysis on December 31, 2019, only 48 were Wake County residents; the remaining 32 patients resided in other counties.
- D. Assuming the 32 patients residing in other counties is a constant, the 20 patients at Oak City and 48 patients at Wake Forest Dialysis (patients residing in Wake County) are increased by application of the Wake County Five Year Average Annual Change Rate of 3.6%. The 32 patients are added at appropriate points in time.

Begin with the combined census of Oak City and Wake Forest patients residing in Wake County as of December 31, 2019.	68
Add the 32 patients residing in other counties.	$68 + 32 = 100^2$
Project the Wake County patient census forward for 12 months to December 31, 2020.	$68 \times 1.036 = 70.4$
Add the 32 patients residing in other counties.	$70.4 + 32 = 102.4$
Project the Wake County patient census forward for 12 months to December 31, 2021.	$70.4 \times 1.036 = 73.0$
Add the 32 patients residing in other counties.	$73.0 + 32 = 105.0$
Project the Wake County patient census forward for 12 months to December 31, 2022.	$73.0 \times 1.036 = 75.6$
Add the 32 patients residing in other counties.	$75.6 + 32 = 107.6$
Project the Wake County patient census forward for 12 months to December 31, 2023.	$75.6 \times 1.036 = 78.3$
Add the 32 patients residing in other counties.	$78.3 + 32 = 110.3$

Thus the following utilization rates are calculated for years indicated:

2020	102.4 patients dialyzing on 32 stations = 3.20 patients per station
2021	105.0 patients dialyzing on 32 stations = 3.28 patients per station
2022	107.6 patients dialyzing on 32 stations = 3.36 patients per station
2023	110.3 patients dialyzing on 32 stations = 3.45 patients per station

<sup>2</sup> See application, page 31; the applicant reports a total of 100 patients as of December 31, 2019.

Thus, using the Wake County Average Annual Change Rate of 3.6%, the applicant continues to have capacity to accept additional patients at its existing facilities. The point of this is to say that despite the assertion by the applicant, no patient would be forced to a third shift.

Siting a facility in an area where the overwhelming majority of the patients would travel further for dialysis is not the best alternative.

Developing a facility in an area where more patients will travel further for dialysis care, when sufficient capacity exists, is not the most effective alternative and certainly leads to unnecessary duplication of existing healthcare resources.

BMA is not suggesting it should direct the business activities of DaVita. BMA is suggesting that the CON process exists with good reason and that it is incumbent upon the applicant to provide credible assumptions to support the application. In this case, it is not credible to suggest that patients would be forced to a third shift when capacity exists within the existing facilities.

**“CRITERION (5)”** - G.S. 131E-183(a)(5)

*“Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.”*

The applicant has not included any costs associated with Central Office Overhead. Surely DaVita incurs a cost associated with the overhead management. There is no indication of costs for the DaVita Teammate Recruiter, or DaVita’s School of Clinical Education (both discussed on page 39 of the application). There is no indication of costs for any of the corporate staff above the Facility Administrator. The cost for corporate overhead are not insignificant.

Further, the applicant has provided unreliable information with regard to the projected payor mix of the facility (see comments with regard to Criterion 13).. The payor mix is a primary consideration when determining the financial viability of the facility. If the payor mix is unreliable, then the resulting projections of revenue are similarly unreliable.

**“CRITERION (6)”** - G.S. 131E-183(a)(6)

*“The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.”*

The applicant has proposed to develop “a new facility at a different location to better serve patients living in the area of the new facility...”<sup>3</sup> However, 19 of the 31 patients signing letters of support do not reside in the area of the new facility. The applicant proposes to

---

<sup>3</sup> See page 39 of the application, response to question 2(a).

create unnecessary duplication of existing and approved healthcare resources. Notwithstanding the fact that new dialysis stations are not created by this application, the applicant suggests that the location for the new facility will enhance access to care. Yet 19 of the 31 patients signing letters of support will have to travel further for dialysis care.

**“CRITERION (12)”** - G.S. 131E-183(a)(12)

*“Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.”*

The applicant has suggested on page 44 that the new facility will have 9,600 square feet. However, the floor plan indicates only 8,570 square feet. This difference of more than 1,000 square feet is material.

**SECTION L - “CRITERION (13)”** - G.S. 131E-183(a)(13)

*“The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:*

- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;*
- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;*
- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and*
- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.”*

The applicant's payor mix projections are questionable, and therefore unreliable.

The applicant includes the following information on page 51 of the application:

***“The projected payor mix is based on the sources of patient payment that have been received (in the last full operating year) by the facilities in the service area. No adjustment rate has been applied to this payor mix so the projected payor mix is the same as that found in Section L-1”. [Emphasis added].***

However, the table on Page 51 is **not** the same as the table on page 50 (responsive to L-1). The following table compares the FY 2019 performance for Wake Forest Dialysis and the projected payor mix for Downtown Raleigh Dialysis Operating Year 2.

In-Center Payor Mix	Wake Forest Dialysis Facility FY 2019	Downtown Raleigh Dialysis Operating Year 2
Self Pay	0.0%	0.0%
Insurance	10.0%	8.0%
Medicare	82.5%	81.0%
Medicaid	7.5%	8.0%
Other (VA)	0.0%	3.0%
Total	100.0%	100.0%

The differences in the projected payor mix is material.

Wake Forest		Year 2 Tx	TXs	Rate / Tx	Extended
Self Pay	0.0%	4533	0	\$	\$
Insurance	10.0%	4533	453.3	\$ 1,285	\$ 582,491
Medicare	82.5%	4533	3739.7	\$ 258	\$ 964,849
Medicaid	7.5%	4533	340.0	\$ 143	\$ 48,616
Other (VA)	0.0%	4533	0	\$ 295	\$
Total	100.0%				\$ 1,595,956
Downtown Raleigh		Year 2 Tx	TXs	Rate / Tx	Extended
Self Pay	0.0%	4533	0	\$	\$
Insurance	8.0%	4533	362.6	\$ 1,285	\$ 465,992
Medicare	81.0%	4533	3671.7	\$ 258	\$ 947,306
Medicaid	8.0%	4533	362.6	\$ 143	\$ 51,858
Other (VA)	3.0%	4533	136.0	\$ 295	\$ 40,117
Total	100.0%				\$ 1,505,273

The above calculations demonstrate a difference of \$90,683 between the payor mix as suggested by the applicant, and the payor mix using the Wake Forest Dialysis facility. This is a material difference.



**SUMMARY:**

The applicant has provided an application which cannot and should not be approved. Therefore the application must be denied.

- The TRC application contains questionable representations of the patient population to be served.
- The applicant has not offered the most effective alternative.
- The applicant has proposed an unnecessary duplication of healthcare resources.
- The applicant has provided internally inconsistent information with regard to the projected size of the facility; there is a difference of more than 1,000 square feet in the floor plan and the applicant's planned development.
- The applicant's projected payor mix is unreliable.

The TRC application fails to conform to CON Review Criterion 3, 4, 5, 6, 12 and 13. The application should not be approved.

If you have any questions please contact me at 910-568-3041, or email [jim.swann@fmc-na.com](mailto:jim.swann@fmc-na.com).

Sincerely,



Jim Swann  
Director of Operations, Certificate of Need

Attachments:

- 1) Map, 27614
- 2) Map, 27616
- 3) Copy of floor plan from CON Project ID # J-11131-16





**TOTAL RENAL CARE OF NORTH CAROLINA, LLC**

**D/B/A**

**OAK CITY DIALYSIS**

**CERTIFICATE OF NEED APPLICATION**

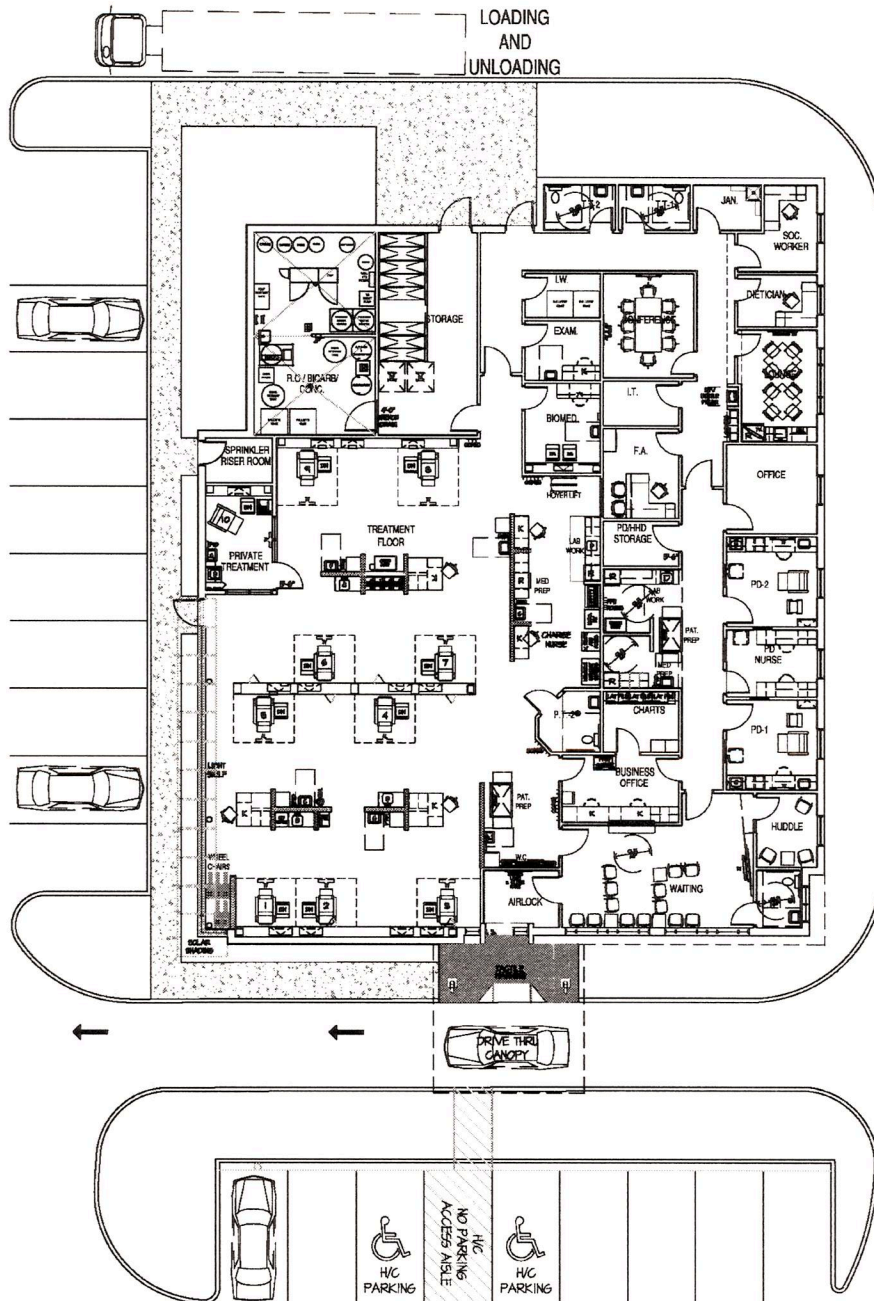
**FEBRUARY 15, 2016**

**FOR THE FACILITY TO BE LOCATED AT**

**3300 RURITANIA STREET  
RALEIGH, NORTH CAROLINA 27616**

**WAKE COUNTY**

**CON - NINE (9) ICHD STATIONS  
AND ONE (1) ISOLATION STATION**



**FLOOR PLAN**  
3/32" = 1'-0" 01-08-2016

**DAVITA INC.**  
**OAK CITY DIALYSIS**  
**OAK CITY, NORTH CAROLINA**

PROTOTYPE:	HOPE
DEVELOPMENT:	DENOV0
TOTAL AREA:	7,969 S.F.

NO.	DATE	DESCRIPTION
1		NC-CON 77



OAK CITY DIALYSIS  
NC - CON 77  
OAK CITY, NORTH CAROLINA

FACILITY# - UNKNOWN  
DOC: DAVID GEARY  
AVANTI / TITAN

PROJECT	+ 2' APPROXIMATE
DESIGNER	+ EDWARD D.M.
ARCHITECT	+ F.A.
CONSULTANT	S.O.S./A.I.L.
CLIENT	BIO-MED
DATE	P.M.
SCALE	D.M.
PROJECT	P.M.
DATE	P.M.

**ALEX ROUSH ARCHITECTS INC.**  
2255 GUMBERLAND PARKWAY  
BUILDING 100  
ATLANTA, GEORGIA 30338  
(770) 333-7878  
FAX 333-7802  
PROJECT NUMBER: 15173  
DRAWN BY: RCA