

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: May 10, 2024

Findings Date: May 10, 2024

Project Analyst: Chalice L. Moore

Co-Signer: Michael McKillip

Project ID #: J-12497-24

Facility: Oak City Dialysis

FID #: 160068

County: Wake

Applicant: Total Renal Care of North Carolina, LLC

Project: Add no more than 12 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 32 stations upon project completion

### REVIEW CRITERIA

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.

C

Total Renal Care of North Carolina, LLC (hereinafter referred to as “the applicant” or “Oak City Dialysis”) proposes to add no more than 12 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 32 stations upon project completion.

#### **Need Determination Condition**

Chapter 9 of the 2024 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table 9B, the county need methodology shows there is no county need determination for additional dialysis stations in Wake County.

However, the applicant is eligible to apply for additional dialysis stations in an existing facility pursuant to Condition 2 of the facility need methodology in the 2024 SMFP, if the utilization rate for the facility as reported in the 2024 SMFP is at least 75 percent or 3.0 patients per station per week, as stated in Condition 2.a. The utilization rate reported for the facility is 75% or 3 patients per station per week, based on 60 in-center dialysis patients and 20 certified dialysis stations (60 patients /20 stations = 3.00, 3.0 / 4 = 75%).

As shown in Tabel 9E, based on the facility need methodology for dialysis stations, the potential number of stations needed is up to 12 additional stations: thus, the applicant is eligible to apply to add up to 12 stations during the 2024 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than 12 new stations to the facility, which is consistent with the 2024 SMFP calculated facility need determination for up to 12 stations pursuant to Condition 2 of the facility need methodology for a total of no more than 32 stations upon project completion; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

### **Policies**

There is one policy in the 2024 SMFP that is applicable to this review, Policy GEN-3: Basic Principles.

Policy GEN-3:

*“Basic Principles A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”*

### **Promote Safety and Quality**

The applicant describes how the proposed project will promote safety and quality in Section B, pages 20 and 21; Section N, pages 76; Section O, pages 79-80; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote safety and quality.

### **Promote Equitable Access**

The applicant describes how the proposed project will promote equitable access in Section B, pages 21 and 22; Section C, pages 31-32; Section L, pages 68-70; section N page 76 and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant's proposal will promote equitable access.

### Maximize Healthcare Value

The applicant describes how the proposed project will maximize healthcare value in Section B, page 22; Section N, page 76; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant's proposal will maximize healthcare value.

### Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion based on the following:

- The applicant adequately demonstrates that the application is consistent with the facility need methodology as applied from the 2024 SMFP.
- The applicant adequately demonstrates that the application is consistent with Policy GEN-3 based on the projects proposed incorporation of safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended.

- (2) Repealed effective July 1, 1987.
- (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, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

### C

Oak City Dialysis proposes to add no more than 12 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 32 stations upon project completion.

### Patient Origin

Page 113 of the 2024 SMFP defines the service area for dialysis stations as "*the county in which the dialysis station is located*". Thus, the service area for this facility consists of Wake County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates historical and projected patient origin.

Oak City Dialysis Historical & Projected Patient Origin												
	Historical – CY 2023						Projected – CY 2027					
	IC Patients		HH Patients		PD Patients		IC Patients		HH Patients		PD Patients	
	#	%	#	%	#	%	#	%	#	%	#	%
Wake	60	89.6%	2	50.00%	10	76.90%	116.3	94.3%	6	75.0%	14	82.35%
Franklin	1	1.5%	1	25.00%	0	0%	1	0.8%	1	12.5%	0	0.0%
Johnston	2	3.0%	1	25.00%	0	0%	2	1.6%	1	12.5%	0	0.0%
Warren	1	1.5%	0	0.0%	0	0%	1	0.8%	0	0.0%	0	0.0%
Other States	3	4.5%	0	0.0%	1	7.69%	3	2.4%	0	0.0%	1	5.88%
Harnett	0	0.0%	0	0.0%	1	7.69%	0	0.0%	0	0.0%	1	5.88%
Chatham	0	0.0%	0	0.0%	1	7.69%	0	0.0%	0	0.0%	1	5.88%
<b>Total</b>	<b>67</b>	<b>100%</b>	<b>4</b>	<b>100%</b>	<b>13</b>	<b>100.0%</b>	<b>123.3</b>	<b>100.0%</b>	<b>8</b>	<b>100%</b>	<b>17</b>	<b>100.0%</b>

Source Section C, pages 25-26

The applicant states the facility currently offers and will continue to offer home hemodialysis and peritoneal dialysis training and support services upon project completion.

In Section C, pages 25-26, and the Form C Utilization subsection of Section Q page 87, the applicant provides the assumptions and methodology used to project patient origin. The applicant’s assumptions are reasonable and adequately supported because they are based on the historical (CY2023) patient origin for the facility.

**Analysis of Need**

In Section C, pages 28-29, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

*“There is a facility need determination of 12 stations for Oak City Dialysis, which had 20 existing stations, as reported in Tables 9D and 9A of the 2024 SMFP. In Section C, Question 3 we demonstrate that an additional 12 stations will be well utilized by the population to be served, the current and projected in-center patients of Oak City Dialysis. The addition of stations serves to increase capacity and proactively address the issues of growth and access at the facility. Dialysis patients spend a significant amount of time in their facilities preparing for and receiving treatment -- three times a week for in-center patients. The additional stations provide opportunities to open appointment times on the more desirable first shift.”*

The information is reasonable and adequately supported based on the following:

- The applicant demonstrates eligibility to add dialysis stations to its facility under Condition 2 of the facility need methodology, as stated in the 2024 SMFP. The discussion regarding need methodology found in Criterion (1) is incorporated herein by reference.

- The applicant adequately demonstrates need based on the facility’s projected growth in the patient population.

Projected Utilization

*In- Center Utilization*

In Section C, pages 27, and in Form Utilization C Section Q, the applicant provides the in-center projected utilization for Wake County, as illustrated in the following table.

Oak City Dialysis	In-Center Stations	In-Center patients
The applicant begins with the station count and patient census at the facility as of 12/31/2023.	20	67
The facility’s Wake County patient census is projected forward a year to 12/31/2024 and increased by 18%.		$60 \times 1.18 = 70.800$
The patients from outside Wake County are added to the facility’s census. This is the ending census for the first interim year.		$70.80 + 7 = 77.80$
The facility’s Wake County patient census is projected forward one year to 12/31/2025 and is increased by 18.0%.		$70.80 \times 1.18 = 83.544$
The patients from outside Wake County are added to the facility’s census. This is the ending census for the second interim year.		$83.54 + 7 = 90.54$
The proposed project is projected to be certified on 01/01/2026. This is the station count at the beginning of the project’s first full fiscal year (FY1). The facility’s Wake County patient census is projected forward one year to 12/31/2026 and is increased by 18.0%.	$20 + 12 = 32$	$83.54 \times 1.18 = 98.58192$
The patients from outside Wake County are added to the facility’s census. This is the ending census for Operating Year 1.		$98.58 + 7 = 105.58$
The facility’s Wake County patient census is projected forward a year to 12/31/2027 and is increased by 18.0%.		$98.58 \times 1.18 = 116.32667$
The patients from outside Wake County are added to the facility’s census. This is the ending census for Operating Year 2.		$116.33 + 7 = 123.33$

Source: Section C, page 27

In Section C, pages 26-28, and in the Form C Utilization subsection of Section Q, the applicant provides the assumptions and methodology used to project patient utilization, which are summarized below.

- Projections for patient utilization begin with the patient population at Oak City Dialysis as of December 31, 2023. The census, as reported in the facility’s December 2024 ESRD Data Collection form, included 67 in-center patients. Of these 67 patients, 60 lived in the service area, Wake County and 7 lived outside of the service area. This data is detailed in the table at Section C, Question 2.
- The first full FY is projected to begin January 1, 2026, and end on December 31, 2026. The second full FY is projected to begin January 1, 2027, and end on December 31, 2027.
- While the Average Annual Change Rate for the Past Five Years (5YAACR) as indicated in Table 9B of the 2024 SMFP was 1.2% for Wake County, the applicant states the facility’s growth has been significantly higher:

On page 27, the applicant provides the following table showing the historical growth in the utilization at Oak City Dialysis:

Oak City Dialysis	IC Pt Census	
12/31/2019	20	
12/31/2020	32	60.0%
12/31/2021	40	25.0%
12/31/2022	60	50.0%
12/31/2023	67	11.7%
5YAACR		36.7%

Source: Section C page 27

*Home Hemodialysis and Peritoneal Dialysis Methodology:*

In Section C, pages 28, and Section Q, the applicant provides the projected utilization for home hemodialysis and peritoneal dialysis as illustrated in the following table:

Wake County	Home Hemodialysis	Peritoneal Dialysis
The applicant begins with the 4 HHD patients and 13 PD patients as of 12/31/2023.	4	13
The facility's home patient census is projected forward a year to 12/31/2024.	4 + 1 = 5	13 + 1 = 14
The facility's home patient census is projected forward a year to 12/31/2025.	5 + 1 = 6	14 + 1 = 15
The facility's home patient census is projected forward a year to 12/31/2026.	6 + 1 = 7	15 + 1 = 16
The facility's home patient census is projected forward a year to 12/31/2027.	7 + 1 = 8	16 + 1 = 17

Source: Section C page 28

- The period of the growth begins January 1, 2024, and is calculated forward to December 31, 2027. The Oak City Dialysis home program trained 2 HD patients and 11 PD patients in 2023. For a variety of reasons, not all patients who are trained to perform home dialysis stay on the modality (transplant, medically necessary modality change, patient choice, etc.). The following home patient projections assume that the facility's home-training program will grow at a rate of at least one patient per year during the period of growth for each modality.
- Projections for patient utilization begin with the patient population at Oak City Dialysis as of December 31, 2023. The census, as reported in the facility's December 2023 ESRD Data Collection form, included 4 HHD patients and 13 PD patients.
- The first full FY is projected to begin January 1, 2026, and end on December 31, 2026. The second full FY is projected to begin January 1, 2027, and end on December 31, 2027.

Projected utilization is reasonable and adequately supported based on the following:

- Oak City Dialysis bases the projections of the future patient population to be served on the facility census as of December 31, 2023
- Oak City Dialysis projects growth of the Wake County patient population based on a growth rate of 18.0% which is less than its most recent experience.

**Access to Medically Underserved Groups**

In Section C, page 33, the applicant states:

*Oak City Dialysis will help uninsured/underinsured patients with identifying and applying for financial assistance; therefore, services are available to all patients including low-income persons, racial and ethnic minorities, women, disabled persons, elderly and other under-served persons.*

*Total Renal Care of North Carolina, LLC and its related facilities in North Carolina have historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for being an underserved person.”*

In Section C, pages 31-32, the applicant provides the estimated percentage of total patients to be served for each medically underserved group, as shown in the following table.

<b>Medically Underserved Groups</b>	<b>Percentage of Total Patients</b>
Low-income persons	82.1%
Racial and ethnic minorities	84.1%
Women	39.0%
Persons with Disabilities	100%
The elderly	40.6%
Medicare beneficiaries	77.6%
Medicaid recipients	3.0%

Source: Section C, page 31-32

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the applicant’s history of providing services to medically underserved groups.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (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, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA



The applicant does not propose to reduce a service, eliminate a service, or relocate a facility or services. Therefore, Criterion (3a) is not applicable to this review.

- (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.

### C

Oak City Dialysis proposes to add no more than 12 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 32 stations upon project completion.

In Section E, page 41, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives were considered:

- **Maintain the status quo.** The applicant states This alternative was dismissed given the growth rate at the facility.
- **Relocate stations from another DaVita facility.** DaVita operates two other facilities in the area. Durham Regional Dialysis opened in August of 2023 and relocating stations from this facility would bring it to below 10 stations. Wake Forest Dialysis Center is operating at greater than 75% capacity. The applicant states relocating stations from this facility would negatively impact the facility's operations and the patients presently served by this facility as it would disrupt patient scheduling and operational efficiencies at the facility.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

1. **Total Renal Care of North Carolina, LLC. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**

2. Pursuant to Condition 2 of the facility need determination in the 2024 SMFP, the certificate holder shall develop no more than 12 additional dialysis stations for a total of no more than 32 stations at the Oak City Dialysis upon completion of this project.
  3. Progress Reports:
    - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.
    - b. The certificate holder shall complete all sections of the Progress Report form.
    - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.
    - d. The first progress report shall be due October 1, 2024.
  4. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.
- (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.

C

Oak City Dialysis proposes to add no more than 12 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 32 stations upon project completion.

Capital and Working Capital Cost

In Section F, page 43, the applicant projects a capital cost of \$192,240, as shown in the table below. The assumptions used to project capital cost in Form F. 1a Capital Cost are provided in Section Q.

Capital Cost	
Medical Equipment	\$162,000
Non-Medical Equipment	\$12,240
Furniture	\$18,000
<b>Total Capital Cost</b>	<b>\$192,240</b>

Source: Section F page 43

In Section F, page 44, the applicant states there are no projected working capital costs because it is an existing facility that is already operational.

Availability of Funds

In Section F, page 43, the applicant projects the capital cost of the project, as shown in the table below.

Source of Financing for Working Capital	Amount
Loans	\$0
Accumulated Reserves or OE*	\$192,240
Bonds	\$0
Other (Describe)	\$0
<b>Total Financing</b>	<b>\$192,240</b>

\*OE= Owner's Equity **Source:** Section F, page 43

In Exhibit F.2, the applicant provides the Consolidated Balance Sheets, as published in DaVita's Form 10-K for the fiscal year ended December 31, 2023, documenting the company had reported \$380,063,000 in Cash and Cash Equivalents as of December 31, 2023.

In Exhibit F.2c, the applicant provides documentation from DaVita's Chief Accounting Officer that the company has committed cash reserves sufficient to fund the proposed project.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the documentation provided in Exhibit F-2.

### **Financial Feasibility**

The applicant provided pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Form F.2, in Section Q, the applicant projects that revenues will exceed operating expenses in the first two full fiscal years following completion of the project, as shown in the table below:

	1 <sup>st</sup> Full FY CY 2026	2 <sup>nd</sup> Full FY CY 2027
Total Treatment	\$17,793	\$20,519
Total Gross Revenues (Charges)	\$8,246,844	\$9,449,428
Total Net Revenue	\$7,818,003	\$8,954,897
Average Net Revenue per Treatment	\$439	\$436
Total Operating Expenses (Costs)	\$3,984,118	\$4,317,293
Average Operating Expense per Treatment	\$224	\$210
Net Income	\$3,833,885	\$4,637,604

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Forms F.2, F.3 and F.4 in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant adequately explains the assumptions used to project revenue, such as projected reimbursement rates, and operating costs, such as salaries.

- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
  - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
  - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

### C

Oak City Dialysis proposes to add no more than 12 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 32 stations upon project completion.

On page 113, the 2024 SMFP defines the service area for dialysis stations as “...*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” Thus, the service area for this facility consists of Wake County. Facilities may serve residents of counties not included in their service area.

According to Table 9A, pages 129-130 of the 2024 SMFP, there are 20 existing or approved dialysis facilities in Wake County, as shown in the following table:

<b>Dialysis Facility</b>	<b>Certified Stations 12/31/2022</b>	<b>Number In-Center Patients 12/31/2022</b>	<b>Utilization</b>
BMA of Fuquay Varina Kidney Center	29	104	89.66%
BMA of Raleigh Dialysis	50	129	64.50%
Cary Kidney Center	29	79	68.10%
Downtown Raleigh Dialysis	0	0	0.0%
FMC Eastern Wake	15	47	78.33%
FMC Morrisville	13	45	86.54%
FMC New Hope Dialysis	36	113	78.47%
FMC Northern Wake	18	60	83.33%
FMC Wake Dialysis Clinic	50	182	91.00%
Fresenius Kidney Care Holly Springs	10	0	0.00%
Fresenius Kidney Care Knightdale	0	0	0.00%
Fresenius Medical Care Apex	20	66	82.50%
Fresenius Medical Care Central Raleigh	19	50	65.79%
Fresenius Medical Care Millbrook	17	59	86.76%
Fresenius Medical Care Rock Quarry	0	0	0.00%
Fresenius Medical Care White Oak	20	71	88.75%
Oak City Dialysis	20	60	75.00%
Southwest Wake County Dialysis	30	113	94.17%
Wake Forest Dialysis Center	21	72	85.71%
Zebulon Kidney Center	30	74	61.67%

Source: Table 9A in the 2024 SMFP.

In Section G, page 51, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Wake County. The applicant states:

*“This application is to add no more than 12 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 32 stations upon project completion. The need addressed by this application is not specific to Wake County as a whole. The station is needed by the patient population projected to be served at the facility”.*

The applicant adequately demonstrates that the proposal will not result in an unnecessary duplication of existing or approved services in the service area based on the following:

- The applicant proposes to increase the number of dialysis stations at Oak City Dialysis based on Condition 2 of the facility need determination in the 2024 SMFP.
- The applicant adequately demonstrates that the 12 proposed dialysis stations are needed in addition to the existing or approved dialysis stations in Wake County.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

Oak City Dialysis proposes to add no more than 12 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 32 stations upon project completion.

In Section Q, Form H, pages 101-102, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table:

Position	Current FTE Staff	Projected FTE Staff	Projected FTE Staff
	As of 2/29/2024	Year 1 CY2026	Year 2 CY2027
Administrator (FMC Clinic Manager)	1.00	1.00	1.00
Registered Nurses (RNs)	2.50	4.00	4.00
Licensed Practical Nurse	0.00	0.00	0.00
Home Training Nurse	0.50	0.50	0.50
Technicians (PCT)	7.50	12.00	12.00
Medical Records	0.00	0.00	0.00
Dietician	0.50	1.00	1.00
Social Worker	0.50	1.00	1.00
Housekeeping	0.00	0.00	0.00
Maintenance	0.00	0.00	0.00
Administration/Business Office	1.00	1.00	1.00
Other (Describe)- Biomedical Tech	0.50	0.50	0.50
<b>Total</b>	<b>14.00</b>	<b>21.00</b>	<b>21.00</b>

Source: Section Q, Form H Staffing

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.4. In Section H, pages 53-54, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The facility is an existing facility, and the applicant bases its staffing on its historical experience providing dialysis services at the facility.
- The applicant has existing policies regarding recruitment, qualifications for staff, training, and continuing education.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

Oak City Dialysis proposes to add no more than 12 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 32 stations upon project completion.

### **Ancillary and Support Services**

In Section I, page 56, the applicant identifies the necessary ancillary and support services for the proposed services. On page 55-59, the applicant explains how each ancillary and support service is or will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available.

### **Coordination**

In Section I, page 59, the applicant describes its existing and proposed relationships with other local health care and social service providers. The applicant adequately demonstrates that the

proposed services will be coordinated with the existing health care system based on its established relationships with other physicians and hospitals in the area and its agreements for lab services, hospital affiliation and transplant.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
  - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
  - (iii) would cost no more than if the services were provided by the HMO; and
  - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (11) Repealed effective July 1, 1987.



- (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.

NA

The applicant does not propose to construct any new space or renovate any existing space. Therefore, Criterion (12) is not applicable to this review.

- (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 ... persons [with disabilities], 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;

C

In Section L, page 68, the applicant provides the historical payor mix for CY2023 as shown in the table below.

Oak City Dialysis						
Payment Source	In-Center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients
Self-Pay	1	1.5%	0	0.0%	0	0.0%
Insurance*	12	17.9%	0	0.0%	6	46.2%
Medicare*	52	77.6%	4	100.0%	7	53.8%
Medicaid*	2	3.0%	0	0.0%	0	0.0%
Other misc. including VA	0	0.0%	0	0.0%	0	0.0%
<b>Total</b>	<b>67</b>	<b>100.0%</b>	<b>4</b>	<b>100.0%</b>	<b>13</b>	<b>100.0%</b>

\* Including any managed care plans.

In Section L, page 69, the applicant provides the following population comparison of the service area.

Oak City Dialysis	Percentage of Total Patients Served (All modalities combined)	Percentage of the Population of the Service Area where the Stations will be Located or Services Offered*
Female	39.1%	50.9%
Male	60.9%	49.1%
Unknown	0.0%	0.0%
64 and Younger	59.4%	87.0%
65 and Older	40.6%	13.0%
American Indian	0.0%	0.8%
Asian	4.3%	8.9%
Black or African-American	66.7%	20.8%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	15.9%	66.6%
Other Race	13.0%	2.8%
Declined / Unavailable	-	-

Sources: BMA Internal Data, US Census Bureau

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately documents 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. Therefore, the application is conforming to this criterion.

- (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 persons with disabilities to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 70, the applicant states it has no such obligation.

In Section L, pages 70, the applicant states that during the 18 months immediately preceding the application deadline no patient civil rights access complaints have been filed against Oak City Dialysis.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (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

C

In Section L, page 71, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

<b>Oak City Dialysis Projected Payor Mix CY2027</b>						
<b>Payment Source</b>	<b>In-Center</b>		<b>HH</b>		<b>PD</b>	
	<b># Patients</b>	<b>% Patients</b>	<b># Patients</b>	<b>% Patients</b>	<b># Patients</b>	<b>% Patients</b>
Self-Pay	1.84	1.5%	0.00	0.0%	0.00	0.0%
Insurance*	22.09	17.9%	0.00	0.0%	7.85	46.2%
Medicare*	95.72	77.6%	8.00	100.0%	9.15	53.8%
Medicaid*	3.68	3.0%	0.00	0.0%	0.00	0.0%
Other-VA	0.00	0.0%	0.00	0.0%	0.00	0.00%
<b>Total</b>	<b>123.33</b>	<b>100.00</b>	<b>8.00</b>	<b>100.0%</b>	<b>17.00</b>	<b>100.0%</b>

\*Including any managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 77.6 percent of in-center patients will be Medicare recipients, 3 percent of in-center services will be provided to Medicaid recipients.

On pages 71-72, the applicant provides the assumptions and methodology it uses to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical payor mix at Oak City Dialysis.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (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.

C

In Section L, page 72, the applicant adequately describes the range of means by which patients will have access to the proposed services.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

Oak City Dialysis proposes to add no more than 12 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 32 stations upon project completion.

In Section M, page 74, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-2. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following:

- The applicant provides a copy of a letter sent to Wake Technical Community College offering the facility as a training site for nursing students.
- Oak City Dialysis has offered the facility as a clinical learning site for nursing students from Wake Technical Community College.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.
  
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

Oak City Dialysis proposes to add no more than 12 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 32 stations upon project completion.

On page 113, the 2024 SMFP defines the service area for dialysis stations as “...*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” Thus, the service area for this facility consists of Wake County. Facilities may serve residents of counties not included in their service area.

According to Table 9A on pages 129-130 of the 2024 SMFP, there are twenty existing or approved dialysis facilities in Wake County. Information on all twenty of these dialysis facilities is provided in the table below.

Dialysis Facility	Certified Stations 12/31/2022	Number In-Center Patients 12/31/2022	Utilization
BMA of Fuquay Varina Kidney Center	29	104	89.66%
BMA of Raleigh Dialysis	50	129	64.50%
Cary Kidney Center	29	79	68.10%
Downtown Raleigh Dialysis	0	0	0.0%
FMC Eastern Wake	15	47	78.33%
FMC Morrisville	13	45	86.54%
FMC New Hope Dialysis	36	113	78.47%
FMC Northern Wake	18	60	83.33%
FMC Wake Dialysis Clinic	50	182	91.00%
Fresenius Kidney Care Holly Springs	10	0	0.00%
Fresenius Kidney Care Knightdale	0	0	0.00%
Fresenius Medical Care Apex	20	66	82.50%
Fresenius Medical Care Central Raleigh	19	50	65.79%
Fresenius Medical Care Millbrook	17	59	86.76%
Fresenius Medical Care Rock Quarry	0	0	0.00%
Fresenius Medical Care White Oak	20	71	88.75%
Oak City Dialysis	20	60	75.00%
Southwest Wake County Dialysis	30	113	94.17%
Wake Forest Dialysis Center	21	72	85.71%
Zebulon Kidney Center	30	74	61.67%

**Source:** Table 9A, Chapter 9, 2024 SMFP, page 119

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 76, the applicant states:

*“The expansion of Oak City Dialysis will have no effect on competition in Wake County. Although the addition of stations at this facility could serve to provide more patients another option to select a provider that gives them the highest quality service and better meets their needs, this project primarily serves to address the needs of a population already served (or projected to be served, based on historical growth rates) by DaVita.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 76, the applicant states:

*“The expansion of Oak City Dialysis will enhance accessibility to dialysis for current and projected patients and, by reducing the economic and physical burdens on our patients, this project will enhance the quality and cost effectiveness of our services because it will make it easier for patients, family members and others involved in the dialysis process to receive services. As noted in Form H, with additional capacity, greater operational efficiency is possible which positively impacts cost effectiveness.”*

See also Sections C, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 76, the applicant states:

*“As discussed in Section B and Section O, DaVita is committed to providing quality care to the ESRD population and, by policy, works to make every reasonable effort to accommodate all of its patients”.*

See also Sections B, C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 76, the applicant states:

*“As discussed in Section C, Question 6, and documented in Exhibit L.5, the facility will serve patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability and, by policy, works to make every reasonable effort to accommodate all of its patients.”*

*“Total Renal Care of North Carolina, LLC related facilities in North Carolina have historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, [disability], age or any other grouping/category or basis for being an underserved person. Low income and medically underinsured persons will continue to have access to all services provided by Total Renal Care of North Carolina, LLC related facilities.”*

See also Sections C and L of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant’s representations about how it will ensure the quality of the proposed services and the applicant’s record of providing quality care in the past.

- 3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion based on all the reasons described above.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

### C

Oak City Dialysis proposes to add no more than 12 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 32 stations upon project completion.

On Form O, pages 79-81, in Section Q, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 107 existing or approved kidney disease treatment facilities located in North Carolina.

In Section O, page 81, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents resulting in an Immediate Jeopardy violation that occurred in any of these facilities. After reviewing and considering information provided by the applicant and considering the quality of care provided at all 107 facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

G.S. 131E-183 (b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being



appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The application is conforming to all applicable criteria, as discussed below.

**10 NCAC 14C .2203 PERFORMANCE STANDARDS**

*(a) An applicant proposing to establish a new kidney disease treatment center or dialysis facility shall document the need for at least 10 dialysis stations based on utilization of 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the facility. An applicant may document the need for less than 10 stations if the application is submitted in response to an adjusted need determination in the State Medical Facilities Plan for less than 10 stations.*

-NA- Oak City Dialysis is an existing facility. Therefore, this Rule is not applicable to this review.

*(a) An applicant proposing to increase the number of dialysis stations in:*

- (1) an existing dialysis facility; or*
- (2) a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need; shall document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the additional stations.*

-C- In Section C, page 27, and on Form C in Section Q, the applicant projects to serve 123 patients on 32 stations, or a rate of 3.31 in-center patients per station per week (106 patients / 32 stations = 3.31, by the end of the first operating year following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

*(c) An applicant proposing to establish a new dialysis facility dedicated to home hemodialysis or peritoneal dialysis training shall document the need for the total number of home hemodialysis stations in the facility based on training six home hemodialysis patients per station per year as of the end of the first full fiscal year of operation following certification of the facility.*

-NA- The applicant does not propose to establish a new dialysis facility dedicated to home hemodialysis or peritoneal dialysis training. Therefore, this Rule does not apply.

*(d) An applicant proposing to increase the number of home hemodialysis stations in a dialysis facility dedicated to home hemodialysis or peritoneal dialysis training shall document the need for the total number of home hemodialysis stations in the facility based on training six*

*home hemodialysis patients per station per year as of the end of the first full fiscal year of operation following certification of the additional stations.*

- NA- The applicant does not propose to increase the number of home hemodialysis stations. Therefore, this Rule does not apply.
- (e) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section C, pages 26-28, and in the Form C Utilization subsection of Section Q, the applicant provides the assumptions and methodology it used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.