

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: January 31, 2025

Findings Date: January 31, 2025

Project Analyst: Chalice L. Moore

Co-Signer: Mike McKillip

Project ID #: J-12581-24

Facility: Wake Forest Dialysis Center

FID #: 041181

County: Wake

Applicant: Total Renal Care of North Carolina, LLC

Project: Add 3 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of 20 stations upon completion of this project and Project ID # J-12556-24 (Develop a new 10-station dialysis facility)

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 “Wake Forest Dialysis Center”) proposes to add 3 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of 20 stations upon completion of this project and Project ID # J-12556-24 (Develop a new 10-station dialysis facility).

Need Determination (Condition 2)

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 85.71% or 3 patients per station per week, based on 72 in-center dialysis patients and 21 certified dialysis stations (72 patients /21 stations = 3.43, 3.43 / 4 = 85.71%).

As shown in Tabel 9D, based on the facility need methodology for dialysis stations, the potential number of stations needed is up to 3 additional stations: thus, the applicant is eligible to apply to add up to 3 stations during the 2024 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than 3 new stations to the facility, which is consistent with the 2024 SMFP calculated facility need determination for up to 3 stations pursuant to Condition 2 of the facility need methodology; 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 19 and 20; Section N, pages 74; Section O, pages 77-79; 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 20 and 21; Section C, pages 30-31; 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 21; 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

Wake Forest Dialysis Center proposes to add 3 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of 20 stations upon completion of this project and Project ID # J-12556-24 (Develop a new 10-station dialysis facility).

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.

| Wake Forest Dialysis Center Historical & Projected Patient Origin | | | | | | | | |
|--|----------------------|---------------|-------------|---------------|---------------------|---------------|-------------|---------------|
| | Historical – CY 2023 | | | | Projected – CY 2028 | | | |
| | IC Patients | | PD Patients | | IC Patients | | PD Patients | |
| | # | % | # | % | # | % | # | % |
| Wake | 46 | 59.0% | 4 | 66.67% | 42 | 56.8% | 9 | 81.82% |
| Franklin | 17 | 21.8% | 1 | 16.67% | 17 | 23.0% | 1 | 9.09% |
| Granville | 3 | 3.8% | | | 3 | 4.1% | | |
| Iredell | 1 | 1.3% | | | 1 | 1.4% | | |
| Wayne | 1 | 1.3% | | | 1 | 1.4% | | |
| South Carolina | 2 | 2.6% | | | 2 | 2.7% | | |
| Other States | 8 | 10.3% | | | 8 | 10.8% | | |
| Johnston | 0 | 0% | 1 | 16.67% | | | 1 | 9.09% |
| Total | 78 | 100.0% | 6 | 100.0% | 74 | 100.0% | 11 | 100.0% |

Source Section C, pages 24-25

The applicant states the facility currently offers in-center (IC) dialysis as well as training and support for peritoneal dialysis (PD).

In Section C, pages 25-26, and the Form C Utilization subsection of Section Q, 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 three stations for Wake Forest, which has 23 existing stations. DaVita has proposed the relocation of 6 stations from Wake Forest to new 10-station facility in Wake County, Tarheel Place. In Section C, Question 3 we demonstrate that an additional three stations will be well utilized by the population to be served, the current and projected in-center patients of Wake Forest. 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 26, and in Form Utilization C Section Q, the applicant provides the projected utilization for Wake Forest Dialysis Center, as illustrated in the following table.

| Wake Forest Dialysis Center | In-Center Home Dialysis Stations | In- Center Home Dialysis Patients | Peritoneal Patients |
|--|----------------------------------|-----------------------------------|---------------------|
| Station count and patient census at the facility as of 12/31/2023. | 23 | 78 | 6 |
| The facility’s patient census is projected forward a year to 12/31/2024. | 23 | $78 \times 1.0 = 78$ | $6 + 1 = 7$ |
| The facility’s patient census is projected forward a year to 12/31/2025. | 23 | $78 \times 1.0 = 78$ | $7 + 1 = 8$ |
| The facility’s patient census is projected forward a year to 12/31/2026. | 23 | $78 \times 1.0 = 78$ | $8 + 1 = 9$ |
| The proposed project and Proj ID# J-12556-24 is projected to be certified on 1/1/2027. Six stations and four ICHD patients are projected to transfer out of Wake Forest. This is the station count and patient census at the beginning of the project’s first full fiscal year (FY1). | $23 - 6 + 3 = 20$ | $78 - 4 = 74$ | 9 |
| The facility’s patient census is projected forward a year to 12/31/2027. | 20 | $74 \times 1.0 = 74$ | $9 + 1 = 10$ |
| The facility’s patient census is projected forward a year to 12/31/2028. | 20 | $74 \times 1.0 = 74$ | $10 + 1 = 11$ |

Source: Section C, page 26

In Section C, pages 25-26, 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 Wake Forest as of December 31, 2023. The census included 78 in-center (IC) patients and six peritoneal dialysis (PD) patients. Of the 78 IC patients, 46 lived in the service area, Wake County, and 32 lived outside of the service area. Of the 6 PD patients, 4 lived in the service area and 2 lived outside of the service area.
- The period of growth begins January 1, 2024 and is calculated forward to December 31, 2028.

- The first full FY is projected to begin January 1, 2027 and end on December 31, 2027. The second full FY is projected to begin January 1, 2028 and end on December 31, 2028.
- In Project ID# J-12556-24, Total Renal Care of North Carolina, LLC proposed the development of Tarheel Place Dialysis in Wake County by relocating 6 stations from Wake Forest Dialysis Center and 4 stations from Oak City Dialysis. Total Renal Care of North Carolina, LLC indicated in the application that four in-center patients would transfer their care from Wake Forest Dialysis Center to Tarheel Place upon its projected certification date of January 1, 2027.
- The Average Annual Change Rate for the Past Five Years (5YAACR) as indicated in Table 9B of the 2024 SMFP for the in-center patients living in Wake County is 1.2%. The applicant assumes no growth in patient census through the second year of the project.

Peritoneal Dialysis Methodology:

In Section C, pages 29, and Section Q, the applicant provides the projected utilization for peritoneal dialysis as illustrated in the following table:

| Wake Forest Dialysis Center | Peritoneal Dialysis |
|--|----------------------------|
| The applicant begins with the total number PD patients trained during the last FY, ending 12/31/2023. | 6 |
| The total number of home patients trained at the facility is projected forward a year to 12/31/2024. $6 + 1 = 7$ | $6 + 1 = 7$ |
| The total number of home patients trained at the facility is projected forward a year to 12/31/2025 | $7 + 1 = 8$ |
| The total number of home patients trained at the facility is projected forward a year to 12/31/2026 | $8 + 1 = 9$ |
| The total number of home patients trained at the facility is projected forward a year to 12/31/2027. This is the total number of home patients trained in OY1. | $9 + 1 = 10$ |
| The total number of home patients trained at the facility is projected forward a year to 12/31/2028. | $10 + 1 = 11$ |

Source: Section C page 30

- The period of growth begins January 1, 2024, and is calculated forward to December 31, 2027. The Wake Forest Dialysis Center trained 6 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 Wake Forest Dialysis Center as of December 31, 2023. The census, as reported in the facility’s December 2023 ESRD Data Collection form, 6 PD patients.
- The first full FY is projected to begin January 1, 2027, and end on December 31, 2027. The second full FY is projected to begin January 1, 2028, and end on December 31, 2028.

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

- Wake Forest Dialysis Center bases the projections of the future patient population to be served on the facility census as of December 31, 2023
- The applicant does not project any growth in the IC patient census through the second year of the project.

Access to Medically Underserved Groups

In Section C, pages 30 and 31, the applicant states:

“By policy, the proposed services will be made available to all residents in the service area without qualifications. The facility will serve patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability and socioeconomic groups of patients in need of dialysis. We will make every reasonable effort to accommodate all patients, especially those with special needs such as those with disabilities, patients attending school or patients who work. Dialysis services will be provided six days per week with two patient shifts per day to accommodate patient need. Wake Forest 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.”

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

| Medically Underserved Groups | Estimated Percentage of Total Patients during the Second Full Fiscal Year |
|-------------------------------------|--|
| Low-income persons | 88.5% |
| Racial and ethnic minorities | 76.5% |
| Women | 41.2% |
| Persons with Disabilities | 100.0% |
| Persons 65 and older | 54.1% |
| Medicare beneficiaries | 87.2% |
| Medicaid recipients | 1.3% |

Source: Section C, page 31

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

Wake Forest Dialysis Center proposes to add 3 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of 20 stations upon completion of this project and Project ID # J-12556-24 (Develop a new 10-station dialysis facility).

In Section E, page 40, 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.** This alternative was dismissed given that, even with a flat growth rate, the utilization rate will remain high if the facility capacity issue is not addressed, and this proposal also proactively addresses the impact of Project ID# J-12556-24.
- **Relocate stations from another DaVita facility.** Of the two other DaVita facilities in Wake County, one is operating at greater than 75% capacity and the other is a 10-station facility which opened six months ago. Relocating stations from Oak City Dialysis or Downtown Raleigh Dialysis would negatively impact access for the patients presently served by each facility as well as disrupt patient and teammate scheduling 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 3 dialysis stations for a total of no more than 20 stations at Wake Forest Dialysis Center upon completion of this project and Project ID # J-12556-24 (Develop a new 10-station dialysis facility).**
 - 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 September 1, 2025.**
 - 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

Wake Forest Dialysis Center proposes to add 3 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of 20 stations upon completion of this project and Project ID # J-12556-24 (Develop a new 10-station dialysis facility).

Capital and Working Capital Cost

In Section F, page 43, the applicant states the proposed project does not require any capital or work capital.

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:

| Wake Forest Dialysis Center | First Full FY CY2027 | Second Full FY CY2028 |
|---|---------------------------------|----------------------------------|
| Total Treatment | 12,375 | 12,523 |
| Total Gross Revenues (Charges) | \$4,401,265 | \$4,490,234 |
| Total Net Revenue | \$4,165,014 | \$4,251,154 |
| Average Net Revenue Per Treatment | \$356 | \$359 |
| Total Operating Expenses (Costs) | \$2,582,646 | \$2,629,144 |
| Average Operating Expense per Treatment | \$209 | \$210 |
| Net Income | \$1,582,368 | \$1,622,009 |

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 because 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

Wake Forest Dialysis Center proposes to add 3 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of 20 stations upon completion of this project and Project ID # J-12556-24 (Develop a new 10-station dialysis facility).

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:

| Wake County Dialysis Facilities | 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 SMFP 2024

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:

“Based on the facility need methodology in the 2024 SMFP under Condition 2, Wake Forest qualifies to add up to three dialysis stations. In Section B, Question 2 and Section C, Question 3 of this application, we demonstrate the need that Wake Forest has for adding stations. While adding stations at this facility does increase the number of stations in Wake County, it is based on the facility need methodology. These stations will “backfill” stations being relocated out of the facility for the project proposed in Proj ID# J-12556-24 (Tarheel Dialysis) and ultimately serve to meet the needs of the facility’s population of patients referred by the facility’s admitting nephrologists. The addition of stations, therefore, serves to

increase capacity rather than duplicate any existing or approved services in the service area.”

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 Wake Forest Dialysis Center based on Condition 2 of the facility need determination in the 2024 SMFP.
- The applicant adequately demonstrates that the 3 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

Wake Forest Dialysis Center proposes to add 3 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of 20 stations upon completion of this project and Project ID # J-12556-24 (Develop a new 10-station dialysis facility)

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 | |
|-----------------------------------|-------------------|---------------------|----------------|
| | As of 10/31/2024 | First Full FY | Second Full FY |
| Administrator | 1.00 | 1.00 | 1.00 |
| Registered Nurses (RNs) | 3.00 | 2.50 | 2.50 |
| Home Training Nurse | 0.50 | 0.50 | 0.50 |
| Technicians (PCT) | 8.75 | 7.50 | 7.50 |
| Dietician | 1.00 | 1.00 | 1.00 |
| Social Worker | 1.00 | 1.00 | 1.00 |
| Administration/Business Office | 1.00 | 1.00 | 1.00 |
| Other (Describe)- Biomedical Tech | 0.50 | 0.50 | 0.50 |
| Total | 16.75 | 15.00 | 15.00 |

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 52-53, 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

Wake Forest Dialysis Center proposes to add 3 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of 20 stations upon completion of this project and Project ID # J-12556-24 (Develop a new 10-station dialysis facility).

Ancillary and Support Services

In Section I, page 55, the applicant identifies the necessary ancillary and support services for the proposed services. On page 55-57, 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 58, 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

- (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 67, the applicant provides the historical payor mix for CY2023 as shown in the table below.

| Wake Forest Dialysis Center | | | | | | |
|-----------------------------|--------------------|---------------|-------------------|-------------|---------------------|---------------|
| Payment Source | In-Center Dialysis | | Home Hemodialysis | | Peritoneal Dialysis | |
| | # Patients | % Patients | # Patients | % Patients | # Patients | % Patients |
| Insurance* | 5 | 6.4% | 0 | 0.0% | 2 | 33.3% |
| Medicare* | 68 | 87.2% | 0 | 0.0% | 4 | 66.7% |
| Medicaid* | 1 | 1.3% | 0 | 0.0% | 0 | 0.0% |
| Other -VA | 4 | 5.1% | 0 | 0.0% | 0 | 0.0% |
| Total | 78 | 100.0% | 0 | 0.0% | 6 | 100.0% |

* Including any managed care plans.

In Section L, page 68, the applicant provides the following population comparison of the service area.

| Wake Forest Dialysis Center | Percentage of Total Patients Served ^ | Percentage of the Population of the Service Area * |
|-------------------------------------|---------------------------------------|--|
| Female | 41.2% | 51.0% |
| Male | 58.8% | 49.0% |
| Unknown | 0.0% | 0.0% |
| 64 and Younger | 45.9% | 86.6% |
| 65 and Older | 54.1% | 13.4% |
| American Indian | 1.2% | 0.8% |
| Asian | 2.4% | 9.4% |
| Black or African-American | 55.3% | 20.6% |
| Native Hawaiian or Pacific Islander | 1.2% | 0.1% |
| White or Caucasian | 23.5% | 57.1% |
| Other Race | 16.5% | 2.9% |
| 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 68, the applicant states that during the 18 months immediately preceding the application deadline no patient civil rights access complaints have been filed against Wake Forest Dialysis Center.

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 69, 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.

| Wake Forest Dialysis Center Projected Payor Mix CY2028 | | | | | | |
|--|---------------|---------------|----------------------|---------------|------------------------|-------------|
| Payment Source | In-Center | | Home Hemodialysis ** | | Peritoneal Dialysis ** | |
| | # Patients | % Patients | # Patients | % Patients | # Patients | % Patients |
| Insurance* | 4.74 | 6.4% | 0.00 | 0.0% | 3.67 | 33.3% |
| Medicare* | 64.51 | 87.2% | 0.00 | 100.0% | 7.33 | 66.7% |
| Medicaid* | 0.95 | 1.3% | 0.00 | 0.0% | 0.00 | 0.0% |
| Other-VA | 3.79 | 5.1% | 0.00 | 0.0% | 0.00 | 0.0% |
| Total | 123.33 | 100.00 | 0.00 | 100.0% | 11.00 | 100% |

*Including any managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 87.2 percent of in-center patients will be Medicare recipients, 1.3 percent of in-center services will be provided to Medicaid recipients.

On page 69, 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 Wake Forest Dialysis Center.

In Section L, page 70, the applicant projects the total number of patients to be served by the entire facility at a reduced cost to the patient in each of the first three full FYs of operation., as illustrated in the following table.

| | 1 st Ful FY | 2 nd Full FY | 3 rd Full FY |
|---|------------------------|-------------------------|-------------------------|
| Estimated # of Patients to be Served at a Reduced Cost to the Patient | 4 | 4 | 4 |

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 70, 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

Wake Forest Dialysis Center proposes to add 3 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of 20 stations upon completion of this project and Project ID # J-12556-24 (Develop a new 10-station dialysis facility).

In Section M, page 72, 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-1. 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.
- Wake Forest Dialysis Center 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

Wake Forest Dialysis Center proposes to add 3 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of 20 stations upon completion of this project and Project ID # J-12556-24 (Develop a new 10-station dialysis facility).

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:

| Wake County 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 in the 2024 SMFP.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 74, the applicant states:

“The expansion of Wake Forest 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. The bottom line is Wake Forest will enhance accessibility and/or convenience to dialysis for our 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. Patient selection is the determining factor, as the patient will select the provider that gives them the highest quality service and best meets their needs.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 74, the applicant states:

“The expansion of Wake Forest 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. 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. 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.”

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 74, 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 74, 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.”

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

Wake Forest Dialysis Center proposes to add 3 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of 20 stations upon completion of this project and Project ID # J-12556-24 (Develop a new 10-station dialysis facility).

On Form O, 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 108 existing or approved kidney disease treatment facilities located in North Carolina.

In Section O, page 79, 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- Wake Forest Dialysis Center 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 32, and on Form C in Section Q, the applicant projects to serve 74 patients on 20 stations, or a rate of 3.7 in-center patients per station per week (74 patients / 20 stations = 3.7), 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, page 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.