

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: December 3, 2024

Findings Date: December 3, 2024

Project Analyst: Crystal Kearney

Co-Signer: Mike McKillip

Project ID #: J-12556-24

Facility: Tarheel Place Dialysis

FID #: 240782

County: Wake

Applicant: Total Renal Care of North Carolina, LLC

Project: Develop a new 10-station dialysis facility by relocating no more than six dialysis stations from Wake Forest Dialysis and no more than four dialysis stations from Oak City Dialysis.

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.

NA

Total Renal Care of North Carolina, LLC (hereinafter referred to as “the applicant” or Tarheel Place Dialysis) proposes to develop a new 10-station dialysis facility by relocating six stations from Wake Forest Dialysis and four stations from Oak City Dialysis. The proposed facility will offer only in-center hemodialysis (ICHD), upon project completion.

The applicant does not propose to develop any beds or services, or acquire any medical equipment for which there is a need determination in the 2024 SMFP, or offer a new institutional health service for which there are any applicable policies in the 2024 SMFP. Therefore, Criterion (1) is not applicable to this review.

- (2) Repealed effective July 1, 1987.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

The applicant proposes to develop a new 10-station dialysis facility by relocating no more than six dialysis stations from Wake Forest Dialysis and no more than four dialysis stations from Oak City Dialysis.

Patient Origin

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 also serve residents of counties not included in their service area.

The proposed project is for a new facility with no historical patient origin data. The following table illustrates the historical patient origin for the existing dialysis stations that will be relocated from Wake Forest Dialysis and Oak City Dialysis as part of this proposal:

Wake Forest Dialysis Historical Patient Origin						
Last Full FY						
CY 2023						
County	# IC Patients	% Total	# HH Patients	% Total	# PD Patients	% Total
Wake	46	59.0%			4	66.67%
Franklin	17	21.8%			1	16.67%
Granville	3	3.8%				
Iredell	1	1.3%				
Johnston	0	0.0%			1	16.67%
Wayne	1	1.3%				
South Carolina	2	2.6%				
Other States	8	10.3%				
Total	78	100.0%	0		6	100.0%

Source: Section C, page 23

Oak City Dialysis Historical Patient Origin						
Last Full FY						
CY 2023						
County	# IC Patients	% Total	# HH Patients	% Total	# PD Patients	% Total
Wake	60	89.6%	2	50.00%	10	76.92%
Franklin	1	1.5%	1	25.00%		
Johnston	2	3.0%	1	25.00%		
Warren	1	1.5%				
Other States	3	4.5%			1	7.69%
Chatham					1	7.69%
Harnett					1	7.69%
Total	67	100.0%	4	100.00%	13	100.00%

Source: Section C, page 23

The following table illustrates projected patient origin for the proposed Tarheel Place Dialysis facility.

Tarheel Place Dialysis Projected Patient Origin						
Second Full FY						
CY 2028						
County	#IC Patients	% Total	#HH Patients	% Total	# PD Patients	%Total
Wake	29.5243	100.0%	0	0%	0	0%
Total	29.5243	100.0%	0	0%	0	0%

Source: Section C, page 24

In Section C, page 24, 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 patient origin for twenty-seven (27) in-center patients who currently receive their dialysis treatments DaVita-operated facilities in Wake County and who live in Wake County and have signed letters indicating they would consider transfer to Tarheel Place. Also, two patients currently receiving dialysis treatments at the applicant's Durham County facilities have signed letters indicating they would consider transfer to Tarheel Place.

The following table summarizes the breakdown of the patient letters detailed above:

ZIP Code of Patient Residence	Downtown Raleigh Dialysis	Oak City Dialysis	Wake Forest Dialysis	Research Triangle Park Dialysis	Durham West	Total
27609		6				6
27603	1	3				4
27604	1	10	1	1	1	14
27607						0
27608						0
27612		2	3			5
Total	2	21	4	1	1	29

Source: Application, page 24

Analysis of Need

In Section C, pages 26-27, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below.

“After a recent evaluation of DaVita’s three Wake County facilities, it was determined that DaVita is serving a total of 29 in-center patients who live in or near the northern part of central Wake County. Dialysis can be a very time-consuming and physically demanding process and sometimes a difference of just a few minutes of travel time can make a significant difference to an individual patient. Twenty-nine (29) Wake County in-center patients have indicated an interest in considering transfer to our proposed facility because it will reduce their travel time and/or be more convenient. In order to make the travel to dialysis (three times a week for in-patients) more convenient for the patients identified in Exhibit C.3, it was determined that DaVita needs to provide a dialysis facility near the northern part of central Wake County, near Duke Raleigh Hospital. This could have a positive effect on their quality of life, and also on their ability and willingness to be more compliant with their treatment schedule.”

This project proposes the development of a new 10-station dialysis facility by relocating stations from two Wake County facilities, six stations (6) from Wake Forest Dialysis and four stations (4) from Oak City Dialysis. Both of these facilities are certified or approved for the maximum number of stations each facility’s physical plant can accommodate without extensive, possibly cost-prohibitive renovations. Relocating stations from Wake Forest Dialysis and Oak City Dialysis will allow for improved access in the identified area of the county, addressing the identified need. It will also make it possible for continued growth in these two existing facilities without the need for significant, and possibly costly, changes to their current physical plant.”

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

- Exhibit C.3 documents the 29 in-center patients who are interested in transferring their care to the proposed facility, located near the Duke Raleigh Hospital, and that the new facility will be more convenient for them.
- The map at Exhibit C.4 displays the proposed site relative to Duke Raleigh Hospital in the northern part of central Wake County, and the three existing Wake County dialysis facilities.

Projected Utilization

In Section Q, Form C, pages 87-89, the applicant provides projected utilization, as illustrated in the following table.

	IC Stations	IC Patients
The applicant begins with the 29 patients dialyzing on 10 stations at the facility as of 01/01/2027	10	29
The facility's Wake County patient census is projected forward a year to 12/31/2027 and is increased by the AACR of 0.09%. This is the census at the end of FY1.		$29 \times 2.009 = 29.2610$
The facility's Wake County patient census is projected forward a year to 12/31/2028 and is increased by the AACR of 0.09%. This is the census at the end of FY2.		$29.261 \times 1.009 = 29.5244$

Source: Sectio C, page 25

The following are the in-center patient projections for the proposed dialysis facility using Wake County's 0.9% Average Annual Change Rate (AACR) for the past five years, as reported in Table 9B of the Proposed 2025 SMFP, for the 29 in-center patients living in Wake County. The period of the growth begins January 1, 2027, and is calculated forward to December 31, 2028.

Projected patients for FY1 and FY2 are rounded to the nearest whole number. Based on the calculations above, by the end of FY1, Tarheel Place is projected to have:

- 29 patients / 10 certified stations = 2.90 patients / station
- $2.90 / 4 = .725$ or 72.5% utilization rate

By the end of FY2, Tarheel Place is projected to have:

- 30 patients / 10 certified stations = 3.00 patients / station
- $3.00 / 4 = .750$ or 75.0% utilization rate

The projected utilization of 2.9 patients per station per week at the end of FY1 exceeds the minimum standard of 2.8 in-center patients per station per week required by 10A NCAC 14C.2203(a).

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

- The applicant's beginning patient census is based on and supported by letter from patients currently receiving dialysis treatment at the applicant's existing dialysis facilities who have indicated an interest in transferring to the proposed Tarheel Place facility.
- The applicant's projected utilization in the first two years of operation is based on and supported by the 5-Year AACR for Wake County.

Access to Medically Underserved Groups

In Section C, pages 28-29, the applicant states,

“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.”

The applicant states 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. The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low income persons	84.1%
Racial and ethnic minorities	73.1%
Women	42.3%
Persons with disabilities	100.0%
Persons 65 and older	46.9%
Medicare beneficiaries	82.1%
Medicaid recipients	2.1%

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 service to all residents of the service area, including underserved groups, without regard for anything other than the need for dialysis 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 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.

C

The applicant proposes to develop a new 10-station dialysis facility by relocating no more than six dialysis stations from Wake Forest Dialysis and no more than four dialysis stations from Oak City Dialysis.

In Section D, page 35-38, the applicant explains why it believes the needs of the population presently utilizing the services to be relocated will be met following completion of the project.

Wake Forest Dialysis

In Section D, page 35, the applicant provides the following table.

Wake Forest Dialysis Center	
County where the facility is located	Wake
1. Total number of existing, approved, and proposed dialysis stations as of the application deadline.	23
2. Number of existing dialysis stations to be reduced, relocated or eliminated in this proposal	-6
3. Total # of dialysis stations upon project completion of this project and all other projects involving this facility.	17

Source: Section D, page 35

In Section D, page 36, the applicant provides a table showing the projected utilization for Wake Forest Dialysis through the first two project years, as summarized below.

	IC Stations	IC Patients
Wake Forest Dialysis Center begins with 78 patients dialyzing on 23 stations at the facility as of 01/01/2024	23	23
The facility's patient census is projected forward a year to 12/31/2024 and is increased by 0%. this is the ending census as of the end of Interim Year 1.		78 x 1.0 = 78
The facility 's patient census projected forward a year to 12/31/2025 and is increased by 0%. This is the ending census as of the end of Interim Year 2.		78 x 1.0 = 78
The facility's patient census is projected forward a year to 12/31/2026 and is increased by 0%. This is the ending census as of the end of Interim Year 3.		78 x 1.0 = 78
Tarheel Place is projected to be certified on 01/01/2027. Six stations and four patients are projected to transfer to Tarheel Place from Wake Forest Dialysis Center.	23-6 = 17	78-4 = 74
This is the station count and in-center census on 01/01/2027	17	74
The facility's patient census projected forward a year to 12/31/2027 and is increased by 0%. This is the ending census as of the end of FY 1.		74 x 1.0 = 74

Section D, page 36

- Projections for patient utilization begin with the patient population at Wake Forest Dialysis Center as of December 31, 2023, as reported in the Proposed 2025 SMFP. There were 78 IC patients at the facility. Of these 78 patients, 46 lived in the service areas, Wake County, and 32 lived outside of the service area.
- The facility's 5YAACR is negative. The applicant states that the facility has had steady growth since 2021.
- The applicant assumes the growth rate remains flat (0%) for the entire patient population.
- The applicant states the four (4) Wake County patients are projected to transfer to Tarheel Place upon certification.

Based on the calculations above, by the end of OY1 Wake Forest Dialysis Center is projected to have:

- 74 patients / 17 certified stations = 4.353 patients / station
- $4.35 / 4 = 1.0824$ or 108.24% utilization rate

On page 36, the applicant states,

“Given this projected growth of the in-center patient population, DaVita will submit additional Certificate of Need applications based on facility need as the facility approaches full capacity of stations to ensure that the needs of the facility’s patients will continue to be met.”

Oak City Dialysis

In Section D, page 37, applicant provides a table showing the number of dialysis stations at Oak City Dialysis, as summarized below.

Oak City Dialysis	
County where the facility is located	Wake
1. Total number of existing, approved, and proposed dialysis stations as of the application deadline	32
2. Number of existing dialysis stations to be reduced, relocated or eliminated in the proposal	4
3. Total number of dialysis stations upon completion of this project and all other projects involving this facility	28

Source: Section D, page 37

In Section D, page 38, the applicant provides a table showing the projected utilization of Oak City Dialysis through the first two project years, as summarized

Oak City Dialysis	Stations	IC Patients
Oak City Dialysis begins with 67 patients dialyzing on 20 stations at the facility as of 01/01/2024.	20	67
The facility's Wake County patient census is projected forward a year to 12/31/2024 and is increased by 15.0%.		$60 \times 1.15 = 69.00$
The 7 patients from outside Wake County are added to the facility's census. This is the ending census as of the end of Interim Year 1.		$69 + 7 = 76$
The facility's Wake County patient census is projected forward a year to 12/31/2025 and is increased by 15.0%.		$69 \times 1.15 = 79.350$
The 7 patients from outside Wake County are added to the facility's census. This is the ending census as of the end of Interim Year 2.		$79.35 + 7 = 86.35$
Project ID# J-12497-24 is projected to be certified on 01/01/2026. This is the station count on 01/01/2026. The facility's Wake County patient census is projected forward a year to 12/31/2026 and is increased by 15.0%.	$20 + 12 + 32$	$79.35 \times 1.15 = 91.25250$
The 7 patients from outside Wake County are added to the facility's census. This is the ending census as of the end of Interim Year 3.		$91.25 + 7 = 98.25$
Tarheel Place is projected to be certified on 01/01/2027. Four stations and 21 Wake County patients are projected to transfer to Tarheel Place from Oak City Dialysis.	$32 - 4 = 28$	$91.25 - 21 = 70.25$ $70.25 + 7 = 77.25$
This is the station count and in-center census on 01/01/2027.	28	77.25
The facility's Wake County patient census is projected forward a year to 12/31/2027 and is increased by 15.0%.		$70.25 \times 1.15 = 80.79038$
The 7 patients from outside Wake County are added to the facility's census. This is the ending census as of the end of FY1.		$80.797 = 87.79$

- Projections for patient utilization begin with the patient population at Oak City Dialysis as of December 31, 2023, as reported in the Proposed 2025 SMFP. There were 67 ICHD patients at the facility. Of these 67 patients, 60 lived in the service area, Wake County, and 7 lived outside of the service area.
- The applicant states in Project ID# J-12497-24, Oak City Dialysis is approved to add 12 stations for a total of 32 stations. The applicant states this expansion is proposed to be certified by January 1, 2026. The applicant states Oak City Dialysis has experienced a 5YAACR of 36.7%. The applicant states projections assume the growth rate will be 15% for the Wake County patients.
- The applicant states that the projections do not apply a growth rate to patients who live outside the service area.

Based on the calculations above, by the end of FY1 Oak City Dialysis is projected to have:

- 88 patients / 28 certified stations = 3.143 patients / station
- $3.143 / 4 = .78571$ or 78.6% utilization rate

On page 38, the applicant states DaVita will submit additional Certificate of Need applications based on facility need as the facility approaches full capacity of stations to ensure that the needs of the facility's patients will continue to be met.

Access to Medically Underserved Groups

The applicant adequately demonstrates that the needs of medically underserved groups that will continue to use dialysis services at Wake Forest Dialysis and Oak City Dialysis will be adequately met following completion of the project for the following reasons:

- The applicant states that the relocation of stations from Oak City Dialysis and Wake Forest Dialysis will have no effect on the ability of low-income persons, racial and ethnic minorities, women, disabled persons, and other under-served group and the elderly to obtain need health care.
- The applicant states that Oak City Dialysis and Wake Forest Dialysis by policy will continue to make dialysis services available to all residents its service area without qualifications.
- The applicant states that Oak City Dialysis and Wake Forest Dialysis will continue to assist 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 underserved persons.

The applicant adequately demonstrates the needs of medically underserved groups will be adequately met following completion of the project based on applicant history of providing care to these 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 the following reasons:

- The applicant adequately demonstrates that the needs of the population currently using the services to be reduced, eliminated or relocated will be adequately met following project completion for all the reasons described above.
- The applicant adequately demonstrates that the project will not adversely impact the ability of underserved groups to access these services following project completion for all the reasons described above.

- (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.

CA

The applicant proposes to develop a new 10-station dialysis facility by relocating no more than six dialysis stations from Wake Forest Dialysis and no more than four dialysis stations from Oak City Dialysis.

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 considered were:

- Maintain the Status Quo: The applicant states maintaining the status quo will not meet the needs of a growing in-center patient population served by DaVita in Wake County, specifically in the identified region of the service area.
- Locating a facility in another area of Wake County: The applicant states that the site proposed for the new facility was selected because it will allow us to provide better geographic access to the patient population identified and reflected in the patient letters at Exhibit C.

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 applicant states that its proposal is the most effective alternative because a facility located in another area of Wake County would not address the need of the patients identified.
- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

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. **The certificate holder shall develop a new 10-station dialysis facility Tarheel Place Dialysis, by relocating no more than six dialysis stations from Wake Forest Dialysis and no more than four dialysis stations from Oak City Dialysis.**
 3. **Upon completion of the proposed project, the certificate holder shall take the necessary steps to decertify six stations at Wake Forest Dialysis for a total of no more than 17 in-center stations upon completion of the project.**
 4. **Upon completion of the proposed project, the certificate holder shall take the necessary steps to decertify four stations at Oak City Dialysis for a total of no more than 28 in-center stations upon completion of the project.**
 5. **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 on April 1, 2025.**
 6. **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

The applicant proposes to develop a new 10-station dialysis facility by relocating no more than six dialysis stations from Wake Forest Dialysis and no more than four dialysis stations from Oak City Dialysis.

Capital and Working Capital Costs

On Form F.1a in Section Q, the applicant projects the total capital cost of the project, as shown in the table below.

Site Costs	\$98,455
Construction Costs	\$2,339,233
Architect/Engineering Fees	\$91,560
Medical Equipment	\$165,360
Non-Medical Equipment	\$432,832
Furniture	\$134,090
Interest during Construction	\$104,369
Total	\$3,365,899

In Section Q, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant states that the Project Manager for North Carolina partnered with Finance to develop the capital cost for this project.
- The applicant identifies the items that are included in each category.

In Section F, pages 44-45, the applicant projects that start-up costs will be \$180,248 and initial operating expenses will be \$632,046 for a total working capital of \$803,294. On page 45, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the following:

- The applicant provided a breakdown of the start up costs which included purchasing inventory of consumable supplies as well as staff labor and training in the timeframe between the completion of leasehold improvements and certification.
- The initial operating expenses were calculated based on to be approximately 50% of the annual budget of OY1.

Availability of Funds

In Section F, page 45, the applicant states that the capital cost will be funded by accumulated reserves. Exhibit F-2c contains a letter dated September 5, 2024, from Chief Accounting Officer of DaVita Kidney Care committing \$4,169,193 for the capital cost and total working capital of the proposed project. In Exhibit F.7, the applicant provides a balance sheets for DaVita Inc., which shows that as December 2023, DaVita Inc., had adequate cash and assets to finance the capital and working capital costs of the proposed project.

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

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 .2, 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.

Tarheel Place Dialysis	CY2027	CY2028
Total Treatments	4,317	4,356
Total Gross Revenues (Charges)	\$1,688,925	\$1,704,125
Total Net Revenue	\$1,584,876	\$1,599,140
Average Net Revenue per Treatment	\$367	\$367
Total Operating Expenses (Costs)	\$1,246,092	\$1,267,908
Average Operating Expense per Treatment	\$289	\$291
Net Income	\$338,784	\$331,232

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Form F.2 and in Form 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 and working 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 revenues and operating expenses for all the reasons described above.
- (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

The applicant proposes to develop a new 10-station dialysis facility by relocating no more than six dialysis stations from Wake Forest Dialysis and no more than four dialysis stations from Oak City Dialysis.

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 page 130 of the 2024 SMFP, there are 20 existing or approved dialysis facilities in Wake County as shown in the following table:

Wake County			
Facility	Certified stations of 12/31/2023	# of IC Patients 12/31/2023	Utilization by% as of 12/31/2023
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	0.00%
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 of the 2024 SMFP

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

“This certificate of need application does not propose increasing the number of stations in Wake County. Transferring 10 stations from Wake Forest Dialysis Center and Oak City Dialysis will create a new facility at a different location to

better serve the identified patients, but it will not result in the duplication of existing services.”

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

- The proposal would not result in an increase in the number of certified dialysis stations in Wake County.
- The applicant adequately demonstrates that the proposed relocation of the existing certified dialysis stations is needed in Wake County.

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.

- (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

The applicant proposes to develop a new 10-station dialysis facility by relocating no more than six dialysis stations from Wake Forest Dialysis and no more than four dialysis stations from Oak City Dialysis.

On Form H in Section Q, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	1 st FFY	2 nd FFY
	CY2027	CY2028
Administrator	1.00	1.00
Registered Nurses (RNs)	1.25	1.25
Licensed Practical Nurses (LPNs)	0.00	0.00
Home Training Nurses	0.00	0.00
Technicians (PCT)	3.75	3.75
Dietician	0.50	0.50
Social Worker	0.50	0.50
Housekeeping	0.00	0.00
Maintenance	0.00	0.00
Administration /Business Office	0.50	0.50
Other Biomedical Tech	0.50	0.50
Total	8.00	8.00

Source: Section Q, Form H, page 102

The assumptions and methodology used to project staffing are provided following Form H 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 Q. In Section H, page 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 applicant states, in Form H Assumptions, that the number of FTE positions is a function of the number of stations available and the patient census to ensure quality care and maximize cost effectiveness.
- The applicant projects sufficient operating expenses for the staff proposed by the applicant.
- The applicant describes the required qualifications for staff, continuing education, and other training programs.

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

The applicant proposes to develop a new 10-station dialysis facility by relocating no more than six dialysis stations from Wake Forest Dialysis and no more than four dialysis stations from Oak City Dialysis.

Ancillary and Support Services

In Section I, page 56, the applicant identifies the necessary ancillary and support services for the proposed services. In Section I, pages 56-58, 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 because DaVita has existing relationships with local health care and social service providers.

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.

C

The applicant proposes to develop a new 10-station dialysis facility by relocating no more than six dialysis stations from Wake Forest Dialysis and no more than four dialysis stations from Oak City Dialysis.

In Section K, page 63, the applicant states that the project involves renovating approximately 8,570 square feet of existing space. Line drawings are provided in Exhibit K-2.

In Section K, pages 63- 65, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following:

- The applicant states that the proposed site is an existing building that will be upfitted to accommodate the provision of daily services, including 10 stations and office space for support staff.
- The applicant states its parent company has extensive experience designing dialysis facilities and incorporating cost-saving measures.

In Section K, page 64, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the following:

- The applicant states the costs of the proposed project are the responsibility of the applicant and the costs are not passed on to patients.
- The applicant states the project will not increase costs or charges to the public for the proposed services.

In Section K, pages 64-66, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit K.3.

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.

- (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 69, the applicant provides the historical payor mix during CY2023 for its existing services at Wake Forest Dialysis and Oak City Dialysis, as shown in the table below.

Payor Source	Wake Forest Dialysis					
	In-center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-Pay	0	0.0%				
Insurance*	7	9.0%				
Medicare*	66	84.6%				
Medicaid*	1	1.3%				
Other-VA	4	5.1%				
Total	78	100.0%				

Payor Source	Oak City Dialysis					
	In-center Dialysis		Home Hemodialysis **		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-Pay	0	0.0%	0	0.0%	0	0.0%
Insurance*	12	17.9%	0	0.0%	6	46.2%
Medicare*	53	79.1%	4	100.0%	7	53.8%
Medicaid*	2	3.0%	0	0.0%	0	0.0%
Other-VA	0	0.0%	0	0.0%	0	0.0%
Total	67	100.0%	4	100.0%	13	100.0%

In Section L, pages 70-71 the applicant provides the following comparison.

Wake Forest Dialysis	Last Full FY Submission of the Application	
	Percentage of Total Patients	Percentage of the Population of the Service Area
Female	41.2%	51.0%
Male	58.8%	49.0%
Unknown		
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%	66.3%
Other Race	16.5%	2.9%
Declined/ Unavailable	NA	NA

Source: Section L, page 70

Oak City Dialysis	Last Full FY before Submission of the Application	
	Percentage of Total Patients Served	Percentage of the Population of the Service Area
Female	43.3%	51.0%
Male	56.7%	49.0%
Unknown		
64 and Younger	60.0%	86.6%
65 and Older	40.0%	13.4%
American Indian	0.0%	0.8%
Asian	2.2%	9.4%
Black or African American	60.0%	20.6%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	30.0%	66.3%
Other Race	7.8%	2.9%
Declined/ Unavailable	NA	NA

Source: Section L, page 71

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 71, the applicant states it has no such obligation.

In Section L, page 71, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights equal access complaints have been filed against Wake Forest Dialysis Center or 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, pages 72, 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.

Tarheel Place Dialysis Projected Payor Mix CY2028		
Payment Source	IC	
	# Patients	% Patients
Insurance*	3.87	13.1%
Medicare*	24.23	82.1%
Medicaid*	0.61	2.1%
Other-VA	0.81	2.8%
Total	29.52	100.0%

*Including any managed care plans
Source: Section L, page 72

As shown in the table above, during the second full fiscal year of operation, the applicant projects 82.1% of services will be provided to Medicare patients; and 2.1% of services will be provided to Medicaid patients.

On pages 84-85, 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 experience of the two existing dialysis facilities.

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 and provides supporting documentation in Exhibit L-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.

- (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

The applicant proposes to develop a new 10-station dialysis facility by relocating no more than six dialysis stations from Wake Forest Dialysis and no more than four dialysis stations from Oak City Dialysis.

In Section M, page 75, 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 applicant provides a copy of a letter sent to Wake Technical Community College offering the facility as a training site for nursing students.

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

The applicant proposes to develop a new 10-station dialysis facility by relocating no more than six dialysis stations from Wake Forest Dialysis and no more than four dialysis stations from Oak City Dialysis.

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 20 existing or approved dialysis facilities in Wake County as shown in the following table:

Wake County			
Facility	Certified stations of 12/31/2023	# of IC Patients 12/31/2023	Utilization by% as of 12/31/2023
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	0.00%
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 of the 2024 SMFP

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 77, the applicant states:

“The patients already being served by DaVita will be transferring their care from one DaVita facility to another DaVita facility, which will be more convenient for the patients who have indicated this in the letters they signed.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 77, the applicant states:

“The development of Tarheel Place 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.”

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

Regarding the impact of the proposal on quality, in Section N, page 77, the applicant states:

“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 and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 77, 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 Section L and C 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

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.

The applicant proposes to develop a new 10-station dialysis facility by relocating no more than six dialysis stations from Wake Forest Dialysis and no more than four dialysis stations from Oak City Dialysis.

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 82, 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 publicly available data considering the quality of care provided at all 108 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.

10A NCAC 14C .2203 PERFORMANCE STANDARDS

(a) An applicant proposing to establish a new dialysis facility for in-center hemodialysis services 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 full fiscal year of operation following certification of the facility. An applicant may document the need for fewer than 10 stations if the application is submitted in response to an adjusted need determination in the State Medical Facilities Plan for fewer than 10 stations.

-C- In Section C.3, pages 24-25, the applicant projects 29 in-center patients will be served by the proposed facility by the end of the first operating year, FY 2027 for utilization rate of 2.8 patients per station per week or 72.5% (29 patients / 10 stations = 2.9 patients per

station / 4 = 0.725) The projected utilization of 2.9 patients per station per week exceeds the 2.9 in-center patients per station threshold required by this rule.

- (b) *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.*

-NA- The applicant is proposing to establish a new ESRD facility.

- (c) *An applicant shall provide all assumptions; including the methodology by which patient utilization is projected. 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. 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 is not proposing to increase the number of home hemodialysis stations in a dialysis facility dedicated to home hemodialysis or peritoneal dialysis training.

- (e) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*

-C- In Section C, pages 24-25, and Form C in 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.