

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: April 29, 2026

Findings Date: April 29, 2026

Project Analyst: Ena Lightbourne

Co-Signer: Micheala Mitchell

Project ID #: J-12726-25

Facility: Downtown Raleigh Dialysis

FID #: 190643

County: Wake

Applicant: Total Renal Care of North Carolina, LLC

Project: Add no more than 4 in-center dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 14 stations upon project completion

REVIEW CRITERIA

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

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

C

Total Renal Care of North Carolina, LLC (hereinafter referred to as “the applicant”) proposes to add no more than four in-center dialysis stations to Downtown Raleigh Dialysis pursuant to Condition 1 of the facility need methodology for a total of no more than 14 stations upon project completion. According to the most recent ESRD Data Collection form, the facility was serving six peritoneal dialysis (PD) patients as of December 31, 2025. The facility did not serve any home hemodialysis patients.

Need Determination (Condition 1)

Chapter 9 of the 2025 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 9C, on page 136 of the 2025 SMFP, the county need methodology

shows there is not a county need determination for additional dialysis stations anywhere in the state. However, the applicant is eligible to apply for additional dialysis stations in an existing facility pursuant to Condition 1 of the facility need methodology in the 2025 SMFP, if the facility is a “new,” “small,” or “new and small” facility as defined in the 2025 SMFP, and if the facility’s current reported utilization is at least 3.0 patients per station per week. “Current” means in-center utilization as of a reporting date no more than 90 days before the date the certificate of need application is submitted. If applying pursuant to Condition 1, the facility may only apply once during the calendar year.

In Section B, page 18 of the application, the applicant reports the following:

Facility Need Methodology Condition 1 (New and Small Facilities Only)	Response
Number of months the facility had been certified as of the data cut-off date in the SMFP	17
Number of stations in the facility as of the data cut-off date in the SMFP	10
According to Table 9A in the 2025 SMFP, the facility is designated as new, small, or new and small	New and Small
Number of stations proposed in this application	4
Number of in-center patients per station as of the current reporting date	3.2
Current Reporting Date (no more than 90 days before the application is submitted)	9/30/2025
Previous Reporting Date (six months prior to the Current Reporting Date)	3/30/2025

Application of the facility need methodology for Condition 1 indicates that up to a potential maximum of 4 additional stations are needed at this facility, as illustrated in the following table.

1	# of In-center Patients as of the Current Reporting Date *	32
2	# of In-Center Patients as of the Previous Reporting Date *	29
3	Subtract Line 2 from Line 1 (Net In-center Change for 6 Months)	3
4	Divide Line 3 by Line 2 (6-month Growth Rate)	0.1
5	Multiply Line 4 by 2 (Annual Growth Rate)	0.2
6	Multiply Line 5 by Line 1 (New Patients)	6.6
7	Add Line 6 to Line 1 (Total Patients)	38.6
8	Divide Line 7 by 2.8 (Total # of Stations Needed)	13.8
9	# of Stations as of the Application Deadline ^A *	10
10	Subtract Line 9 from Line 8 (Additional Stations Needed)	3.8

*Table 9A of the 2025 SMFP reports zero in-center patients at the facility. However, 2025 ESRD Data Collection Form reports 35 in-center patients by December 31, 2025. The Project Analyst concludes that the 2025 ESRD Data Collection Form is sufficient to support the applicant’s reporting of 32 in-center patients by September 30, 2025.

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is 4, based on rounding allowed in Condition 1.b.(vii). Condition 1.c of the facility need methodology states, “*The facility may apply for any number of stations up to the number calculated in Condition 1.b.vii, up to a maximum of 10 stations.*” Downtown Raleigh Dialysis proposes to add four new stations; therefore, the application is consistent with Condition 1 of the facility need determination for dialysis stations.

Policies

There is one policy in the 2025 SMFP which is applicable to this review. *Policy GEN-5: Access to Culturally Competent Healthcare*, on page 30 of the 2025 SMFP, states:

“A certificate of need (CON) applicant applying to offer or develop 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 provide culturally competent healthcare that integrates principles to increase health equity and reduce health disparities in underserved communities. The delivery of culturally competent healthcare requires the implementation of systems and training to provide responsive, personalized care to individuals with diverse backgrounds, values, beliefs, customs, and languages. A certificate of need applicant shall identify the underserved populations and communities it will serve, including any disparities or unmet needs of either, document its strategies to provide culturally competent programs and services, and articulate how these strategies will reduce existing disparities as well as increase health equity.”

CON applications will include the following:

The applicant shall, in its CON application, address each of the items enumerated below:

Item 1: *Describe the demographics of the relevant service area with a specific focus on the medically underserved communities within that service area. These communities shall be described in terms including, but not limited to: age, gender, racial composition; ethnicity; languages spoken; disability; education; household income; geographic location and payor type.*

Item 2: *Describe strategies it will implement to provide culturally competent services to members of the medically underserved community described in Item 1.*

Item 3: *Document how the strategies described in Item 2 reflect cultural competence.*

Item 4: *Provide support (e.g., best-practice methodologies, evidence-based studies with similar communities) that the strategies described in Items 2 – 3 are reasonable pathways for reducing health disparities, increasing health equity and improving the health outcomes to the medically underserved communities within the relevant service area.*

Item 5: Describe how the applicant will measure and periodically assess increased equitable access to healthcare services and reduction in health disparities in underserved communities.”

In Section B, pages 20-21, the applicant explains why it believes its application is conforming to *Policy GEN-5*.

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 2025 SMFP.
- The applicant adequately demonstrates that the proposal is consistent with *Policy GEN-5* based on the following:
 - The applicant adequately describes the demographics of the facility and the service area by citing data from the U.S. Census Bureau that include age, gender, ethnicity, language spoken, and education level.
 - The applicant adequately describes the strategies it will implement to provide cultural competence services. In an effort to ensure healthy outcomes, specifically to Downtown Raleigh Dialysis and its diverse patient population, the applicant will initiate strategies that will eliminate certain barriers, such as offering language assistance services and providing Health Equity and Cultural Humility training to all staff.
 - The applicant states that health equity data will regularly be reviewed to identify potential disparities and subsequently develop plans to address and monitor progress.
 - In Exhibit B.8.c, the applicant provides the Culturally and Linguistically Appropriate Services (CLAS) action plan for ESRD communities that was developed by the ESRD National Coordinating Center. The action plan was adopted from the CLAS program at the federal level that assists health organizations improve quality of care and eliminate health disparities as communities become more diverse.

(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 add no more than four in-center dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 14 stations upon project completion.

In Section C, page 23, the applicant states that Downtown Raleigh Dialysis provides in-center hemodialysis as well as training and support for PD patients. There are 10 certified dialysis stations, as reported in Table 9A of the 2025 SMFP.

Patient Origin

On page 113, the 2025 SMFP defines the service area for dialysis stations as “...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.” Downtown Raleigh Dialysis is located in Wake County. Thus, the service area for this facility consists of Wake County. Facilities may serve residents of counties not included in their service area.

The following tables illustrate historical and projected patient origin.

Downtown Raleigh Dialysis Historical Patient Origin CY2024						
County	In-Center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Wake	11	61.1%			5	83.33%
Durham	1	5.6%			0	0.00%
Johnston	4	22.2%			0	0.00%
Other States	2	11.1%			1	16.67%
Total	18	100.0%	0	0.0%	6	100.00%

Sources: Section C, page 23

Downtown Raleigh Dialysis Projected Patient Origin CY2029						
County	In-Center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Wake	36.0169	81.8%			10	100.00%
Durham	1	2.3%			0	0.00%
Johnston	4	9.1%			0	0.00%
Mecklenburg	1	2.3%			0	0.00%
Nash	1	2.3%			0	0.00%
New Hanover	1	2.3%			0	0.00%
Total	44.0169	100.0%	0	0.0%	10	100.00%

Sources: Section C, page 24

In Section C, page 24, and Section Q, page 84, the applicant provides the assumptions and methodology used to project patient origin. The applicant’s assumptions are reasonable and adequately supported because it is based on the historical patient origin for the facility as of September 30, 2025. The applicant states that the facility census consisted of 24 in-center patients originating from Wake County and eight patients originating Durham, Johnston, Mecklenburg, Nash and New Hanover counties. The applicant projects forward using a 10% growth rate. The applicant states that the growth rate used is reasonable considering the facility’s 260% growth rate of in-center patients from December 31, 2023, through December 31, 2024. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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. On pages 26-27, the applicant states:

“Downtown Raleigh Dialysis has 10 certified stations, as reported in Table 9A of the 2025 SMFP and is designated a new and small facility in the same table... there is a facility need determination of four (4) stations for Downtown Raleigh, pursuant to Condition 1 of the 2025 SMFP...we demonstrate that an additional 4 stations will be well utilized by the population to be served, the facility’s current and projected in-center patients. The addition of stations serves to increase capacity and proactively address the issues of growth and access at this small 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 1 of the facility need methodology, as stated in the 2025 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 and maintaining access to dialysis services at Downtown Raleigh Dialysis.

Project Utilization

In-Center Patients

In Section C, page 25, and Section Q, page 85, the applicant provides projected utilization, as illustrated in the following table.

Downtown Raleigh Dialysis Projected Utilization		
	IC stations	IC patients
Station count and patient census at the facility as of September 30, 2025.	10	32
The facility’s Wake County patient census is projected forward from 10/1/2025 forward to 12/31/2025		$24 \times 1.025 = 24.6$
The patients from outside Wake County are added. This is the ending census for the first partial interim year.		$24.6 + 8 = 32.6$
The facility’s Wake County patient census is projected forward a year to December 31, 2026.		$24.6 \times 1.10 = 27.060$
The patients from outside Wake County are added. This is the ending census for the first full interim full year.		$27.06 + 8 = 35.06$
The facility’s Wake County patient census is projected forward a year to December 31, 2027.		$27.06 \times 1.10 = 29.7660$
The patients from outside Wake County are added. This is the ending census for the second full interim year		$29.77 + 8 = 37.77$
The proposed project is projected to be certified on January 1, 2028. This is the station count at the beginning of the project’s first full fiscal year (FY1).		$10 + 4 = 14$
The facility’s Wake County patient census is projected forward a year to December 31, 2028.		$29.77 \times 1.10 = 32.7426$
The patients from outside Wake County are added. This is the ending census for FY1.		$32.74 + 8 = 40.74$
The facility’s Wake County patient census is projected forward a year to December 31, 2028.		$32.74 \times 1.10 = 36.01686$
The patients from outside Wake County are added. This is the ending census of the project’s second full fiscal year (FY2).		$36.02 + 8 = 44.02$

In Section C, pages 24-29 and Section Q, pages 84-86, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The applicant projects the first fiscal year of the project will be January 1, 2028 - December 31, 2028, and the second full fiscal year will be January 1, 2029 - December 31, 2029.
- The applicant begins with the patient census as of September 30, 2025, which was 32 IC patients on 10 dialysis stations. Of the 32 patients, eight resided outside of Wake County.

- The applicant grew the Wake County patient census using a conservative grow rate of 10%, which is significantly lower than the actual growth since the facility’s certification in April 2023 through December 31, 2024.
- As of December 31, 2025, the facility was serving eight IC patients residing outside of Wake County. The applicant does not project growth for this population and adds these patients to projections of future patient population at the appropriate time.
- The applicant projects a total of 44 in-center patients to be served at Downtown Raleigh Dialysis by the end of the second project year.

The projected utilization rates for the end of the first two full fiscal years upon project completion are as follows:

- FY1: 2.9 patients per station per week or 73.20% (41 patients / 14 stations = 2.928/4 = 0.7320 or 73.20%)
- FY2: 3.1 patients per station per week or 78.55% (44 patients / 14 stations = 3.142 /4 = 0.7855 or 78.55%)

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(b).

Peritoneal Dialysis Patients

In Section Q, Form C, and page 86, the applicant provides projected utilization, as illustrated in the following table.

Downtown Raleigh Dialysis Projected Utilization	
	# of PD Patients
Home patient census at the facility as of 9/30/2025	5
The facility’s home patient census is projected forward a year to 12/31/2025	5 +1 = 6
The facility’s home patient census is projected forward a year to 12/31/2026	6 +1 = 7
The facility’s home patient census is projected forward a year to 12/31/ 2027	7 +1 = 8
The facility’s home patient census is projected forward a year to 12/31/2028	8 +1 = 9
The facility’s home patient census is projected forward a year to 12/31/2029	9 +1 = 10

In Section Q, pages 85-86, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The applicant begins with the number of PD patients served by Downtown Raleigh Dialysis as of September 30, 2025. The facility census consisted of five PD patients and by the end of the year the facility was servicing six PD patients.
- The applicant assumes that the home training program will grow at least one patient per year through the first two project years.

- The applicant projects a total of 10 PD patients to be served at Downtown Raleigh Dialysis by the end of the second project year.

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

- The applicant projects utilization using a conservative growth rate based on the facility's historical growth.
- The applicant's assumptions regarding the growth in the facility's PD patients are supported by factors such as patient choice, increase in referring physicians, and the emphasis on increasing home patients.
- The applicant's proposal to add four dialysis stations will meet the need of the projected growth of the facility's patient population pursuant to Condition 1 of the 2025 SMFP.
- Projected utilization at the end of FY1 exceeds the minimum of 2.8 patients per station per week required by 10A NCAC 14C .2203(b).

Access to Medically Underserved Groups

In Section C, page 30, the applicant states:

“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.

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

In Section C, page 30, 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	78.1%
Racial and ethnic minorities	87.1%
Women	38.7%
Persons with Disabilities	100.0%
Persons 65 and older	31.3%
Medicare beneficiaries	68.8%
Medicaid recipients	9.4%

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 at its existing 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 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 service. 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.

CA

The applicant proposes to add no more than four in-center dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 14 stations upon project completion.

In Section E, page 39, 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 that this alternative was dismissed due to the facility's historical growth rate. According to the most recent ESRD data collection form, the facility had a utilization rate of 87.50% as of December 31, 2025.
- Relocate Stations from Another DaVita Facility-The applicant states that relocating stations from the two other Davita-operated facilities in Wake County would be a less effective alternative. Oak City Dialysis and Wake Forest Dialysis Center are both currently operating above 75.00% capacity. Relocating stations from these facilities would

negatively impact operations. Additionally, both facilities are losing stations to support the development of Tarheel Place Dialysis, a 10-station dialysis facility that was CON-approved December 3, 2024.

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

- The applicant's proposal to add stations to Downtown Raleigh Dialysis is based on the facility's eligibility to add stations under Condition 1 of the facility need methodology, as stated in the 2025 SMFP.
- The applicant provides reasonable information to explain why it believes the proposed project is the most effective alternative.
- 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. Pursuant to Condition 1 of the facility need methodology in the 2025 SMFP, the certificate holder shall add no more than four additional in-center dialysis stations at Downtown Raleigh Dialysis for a total of no more than 14 in-center stations upon project completion.**
- 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 February 1, 2027.**

4. **The certificate holder shall develop and implement strategies to provide culturally competent services to members of its defined medically underserved community that are consistent with representations made in the certificate of need application.**
 5. **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 add no more than four in-center dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 14 stations upon project completion.

Capital and Working Capital Costs

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

Capital Costs	
Medical Equipment	\$54,000
Non-Medical Equipment	\$16,680
Furniture	\$8,000
Total	\$78,680

In Section Q, page 90, 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 that are based on the Project Manager's collaboration with the Real Estate Team, Operations, and Finance to develop a reasonable capital cost for the project.

In Section F, page 42, the applicant states there will be no start-up costs or initial operating expenses because the facility's revenues exceed operating costs.

Availability of Funds

On page 41, the applicant states that the capital cost will be funded by Total Renal Care of North Carolina, LLC, through accumulated reserves.

In Exhibit F-2c, the applicant provides a letter dated October 21, 2025, from John Winstel, Chief Accounting Officer of DaVita Kidney Care, parent company, to Total Renal Care of North Carolina LLC, documenting Mr. Winstel's authority to commit the funds for the capital costs of the project through DaVita's accumulated reserves. Exhibit F-7 includes Davita's December 2024 Consolidated Balance Sheets, documenting over \$700 million in cash and cash equivalents and over \$3 billion in total assets.

The applicant adequately demonstrates the availability of funds for the capital needs of the project.

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, the applicant projects that revenues will exceed operating expenses in the first three full fiscal years following completion of the project, as shown in the table below.

Downtown Raleigh Dialysis	1st Project Year	2nd Project Year
	CY2028	CY2029
Total Treatments	7,077	7,689
Total Gross Revenues (Charges)	\$3,047,679	\$3,322,372
Total Net Revenue	\$3,033,904	\$3,307,407
Average Net Revenue per Treatment	\$429	\$430
Total Operating Expenses (Costs)	\$1,115,590	\$1,118,377
Average Operating Expense per Treatment	\$158	\$145
Net Income	\$1,918,314	\$2,189,030

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's assumptions regarding charges per treatment by payor source are based on the historical experience of existing Davita facilities.
- The applicant adequately explains the assumptions used to project operating costs, such as salaries, depreciation, and mortgage.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
 - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
 - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of 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 add no more than four in-center dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 14 stations upon project completion.

On page 113, the 2025 SMFP defines the service area for dialysis stations as “...*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.*” Downtown Raleigh is located in Wake County. 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 the 2025 SMFP, Table 9A, pages 124-125, there were 21 existing or approved dialysis facilities in Wake County, as shown in the following table.

Wake County					
	Certified Stations as of 12/31/2023*	Number of In-center Patients as of 12/31/2023*	Utilization by Percent as of 12/31/2023*	Patients per Station as of 12/31/2023*	Number of Additional Stations Approved*
BMA of Fuquay Varina Kidney Center	29	103	88.79%	3.5	7
BMA of Raleigh Dialysis	50	113	56.50%	2.3	0
Cary Kidney Center	29	80	68.97%	2.8	0
Downtown Raleigh Dialysis	0	0	0.00%	0.0	0
FMC Eastern Wake	15	54	90.00%	3.6	7
FMC Morrisville	13	41	78.85%	3.2	0
FMC New Hope Dialysis	36	110	76.39%	3.1	2
FMC Northern Wake	20	59	73.75%	3.0	0
FMC Wake Dialysis Clinic	50	177	88.50%	3.5	11
Fresenius Kidney Care Holly Springs	10	21	52.51%	2.1	0
FMC Knightdale	0	0	0.00%	0.0	0
FMC Apex	20	65	81.25%	3.3	3
FMC Central Raleigh	19	51	67.11%	2.7	0
FMC Millbrook	17	60	88.24%	3.5	5
FMC Rock Quarry	0	0	0.00%	0.0	0
FMC White Oak	20	73	91.25%	3.7	7
Oak City Dialysis	20	67	83.75%	3.4	0
Southwest Wake County Dialysis	30	114	95.00%	3.8	9
Tarheel Place Dialysis	0	0	0.00%	0.0	0
Wake Forest Dialysis Center	21	78	92.86%	3.7	13
Zebulon Kidney Center	30	79	65.83%	2.6	0
Total	429	1,345			

*Source: 2025 SMFP, Table 9A, page 129-130

In Section G, page 49, 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 2025 SMFP under Condition 1, Downtown Raleigh Dialysis qualifies to add up to 4 dialysis stations.

...we demonstrate the need that Downtown Raleigh Dialysis 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. It ultimately serves to meet the needs of the facility’s growing 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 would not result in an unnecessary duplication of existing or approved services in the service area based on the following:

- The applicant adequately demonstrates the facility need to add four stations to Downtown Raleigh Dialysis pursuant to Condition 1 of the 2025 SMFP.
- The proposal would not result in unnecessary duplication because the proposal to add stations will expand capacity in response to the facility’s growing patient population.
- The applicant adequately demonstrates that the proposed dialysis stations are needed in addition to the existing or approved dialysis stations.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information 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

The applicant proposes to add no more than four in-center dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 14 stations upon project completion.

In Section Q, Form H, 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 10/31/2025	CY2028	CY2029
Administrator	1.00	1.00	1.00
Registered Nurses (RNs)	1.25	1.75	1.75
Hope Training Nurses	0.50	0.50	0.50
Technicians (PCT)	3.75	5.25	5.25
Dietician	0.50	0.50	0.50
Social Worker	0.50	0.50	0.50
Administration/Business Office	0.50	1.00	1.00
Other- Biomedical Tech	0.50	0.50	0.50
Total	8.50	11.00	11.00

The assumptions and methodology used to project staffing are provided in Section Q, page 98. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.4. In Section H, pages 51-52, 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 adequately describes the tools used to recruit appropriate staff that include DaVita’s Teammate Recruiter and Referral Program and the Student Internship Program.
- Clinical Staff are trained through DaVita’s School of Clinical Education.
- In Exhibit H.3, the applicant provides an outline of DaVita’s in-service training, including a list of courses offered.

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.

The applicant proposes to add no more than four in-center dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 14 stations upon project completion.

Ancillary and Support Services

In Section I, page 54, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 54-56, 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 by describing how most ancillary and support services are already in place to support the additional four stations.

Coordination

In Section I, page 56, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant states that relationships with healthcare providers and social service agencies are already established because the applicant currently provides dialysis services across Wake County.
- In Exhibit I.2, the applicant provides letters from the Facility Administrator and the Medical Director confirming that established agreements and working relationships will continue.

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. Therefore, Criterion (9) is not applicable to this review.

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

NA

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

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

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

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and ... persons [with disabilities], which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L, page 66, the applicant provides the historical payor mix during CY2024 for the proposed services, as shown in the table below.

Downtown Raleigh Dialysis Historical Payor Mix CY2024						
Payor Source	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%
Insurance*	2	12.5%			2	40.0%
Medicare*	12	68.8%			4	60.0%
Medicaid*	2	9.4%			0	0.0%
Other (VA)	2	9.4%			0	0.0%
Total	18	100.0%	0	0.0%	6	100.0%

In Section L, page 67, the applicant provides the following comparison.

Downtown Raleigh Dialysis	Percentage of Total Patients Served	Percentage of the Population of the Service Area*
Female	38.7%	51.0%
Male	61.3%	49.0%
Unknown	0.0%	0.0%
64 and Younger	68.8%	86.6%
65 and Older	31.3%	13.4%
American Indian	0.0%	0.8%
Asian	0.0%	9.4%
Black or African American	71.0%	20.6%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	12.9%	66.3%
Other Race	16.1%	2.9%
Declined / Unavailable	-	-

*The percentages can be found online using the United States Census Bureau's QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>

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 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 67, the applicant states that the facility is not obligated under any applicable federal regulations to provide uncompensated care, community service or access by minorities and persons with disabilities.

In Section L, page 67, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against the facility.

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 68, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

Downtown Raleigh Dialysis Projected Payor Mix CY2029						
Payor Source	In-Center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-Pay	0.00	0.0%			0.00	0.0%
Insurance*	5.50	12.5%			4.00	40.0%
Medicare*	30.26	68.8%			6.00	60.0%
Medicaid*	4.13	9.4%			0.00	0.0%
Other (VA)	4.13	9.4%			0.00	0.0%
Total	44.02	100.0%	0	0.0%	10.00	100.0%

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 0.0% of total in-center services will be provided to self-pay patients, 68.8% to Medicare patients and 9.4% to Medicaid patients.

On page 68, the applicant provides the assumptions and methodology used to project payor mix during third 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 facility's historical payor mix. The applicant does not project any change to the payor mix percentages.

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 reasons stated above.

- (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 69, the applicant adequately describes the range of means by which patients will have access to the proposed services.

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 add no more than four in-center dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 14 stations upon project completion.

In Section M, page 71, 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 states that it has offered Downtown Raleigh Dialysis as a clinical learning site for nursing students from Wake Technical Community College.
- In supporting documentation, the applicant provides a letter dated January 14, 2020 that was sent to Wake Technical Community College prior to its development, offering the facility as a clinical learning site.

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 add no more than four in-center dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 14 stations upon project completion.

On page 113, the 2025 SMFP defines the service area for dialysis stations as “...*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.*” Downtown Raleigh is located in Wake County. 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 the 2025 SMFP, Table 9A, pages 124-125, there were 21 existing or approved dialysis facilities in Wake County, as shown in the following table.

Wake County					
	Certified Stations as of 12/31/2023*	Number of In-center Patients as of 12/31/2023*	Utilization by Percent as of 12/31/2023*	Patients per Station as of 12/31/2023*	Number of Additional Stations Approved*
BMA of Fuquay Varina Kidney Center	29	103	88.79%	3.5	7
BMA of Raleigh Dialysis	50	113	56.50%	2.3	0
Cary Kidney Center	29	80	68.97%	2.8	0
Downtown Raleigh Dialysis	0	0	0.00%	0.0	0
FMC Eastern Wake	15	54	90.00%	3.6	7
FMC Morrisville	13	41	78.85%	3.2	0
FMC New Hope Dialysis	36	110	76.39%	3.1	2
FMC Northern Wake	20	59	73.75%	3.0	0
FMC Wake Dialysis Clinic	50	177	88.50%	3.5	11
Fresenius Kidney Care Holly Springs	10	21	52.51%	2.1	0
FMC Knightdale	0	0	0.00%	0.0	0
FMC Apex	20	65	81.25%	3.3	3
FMC Central Raleigh	19	51	67.11%	2.7	0
FMC Millbrook	17	60	88.24%	3.5	5
FMC Rock Quarry	0	0	0.00%	0.0	0
FMC White Oak	20	73	91.25%	3.7	7
Oak City Dialysis	20	67	83.75%	3.4	0
Southwest Wake County Dialysis	30	114	95.00%	3.8	9
Tarheel Place Dialysis	0	0	0.00%	0.0	0
Wake Forest Dialysis Center	21	78	92.86%	3.7	13
Zebulon Kidney Center	30	79	65.83%	2.6	0
Total	429	1,345			

*Source: 2025 SMFP, Table 9A, page 129-130

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 73, the applicant states:

“...Although the addition of stations at this facility could serve to provide more patients another option to select a provider that gives them the highest quality service and better meets their needs, this project primarily serves to address the needs of a population already served (or projected to be served, based on historical growth rates) by DaVita.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 73, the applicant states:

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

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

Regarding the impact of the proposal on quality, in Section N, page 73, 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 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 73, the applicant states:

“...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 L, B 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.
- 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 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

In Section Q, Form O, 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 105 of this type of facility located in North Carolina.

In Section O, page 78, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to immediate jeopardy had not occurred in any of these facilities. After reviewing and considering information provided by the applicant, and considering the quality of care provided at all 105 facilities, the applicant provided 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 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 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.*

-NA- The applicant is not proposing to establish a new kidney disease treatment center or dialysis facility. Downtown Raleigh Dialysis is an existing facility. Therefore, this Rule is not applicable to this review.

- (b) *An applicant proposing to increase the number of in-center 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 full fiscal year of operation following certification of the additional stations.

-C- In Section C, page 25, and on Form C in Section Q, the applicant projects that Downtown Raleigh Dialysis will serve 41 patients on 14 stations, or a rate of 2.9 patients per station per week, as of the end of the first full fiscal year of operation following certification of the additional stations. 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 is not proposing to establish a new dialysis facility dedicated to home hemodialysis or peritoneal dialysis training. Therefore, this Rule is not applicable to this review.

- (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 in a dialysis facility dedicated to home hemodialysis or peritoneal dialysis training. Therefore, this Rule is not applicable to this review.

- (e) *An applicant shall provide all assumptions, including the methodology used for the projected utilization required by this Rule.*

-C- In Section C, pages 24-29 and Section Q, pages 84-86, 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.