

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: March 25, 2026

Findings Date: March 25, 2026

Project Analyst: Cynthia Bradford

Co-Signer: Mike McKillip

Project ID #: E-12728-26

Facility: Newton Dialysis

FID #: 260023

County: Catawba County

Applicant: Total Renal Care of North Carolina, LLC

Project: Develop a new dialysis facility by relocating no more than 11 dialysis stations from Catawba County Dialysis for a total of no more than 11 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.

NA

Total Renal Care of North Carolina, LLC (hereinafter referred to as “the applicant” or Newton Dialysis) proposes to develop a new 11-station dialysis facility by relocating 11 stations from Catawba County Dialysis. The proposed facility will offer only in-center hemodialysis (ICHHD) 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 2026 SMFP or offer a new institutional health service for which there are any applicable policies in the 2026 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- (2) Repealed effective July 1, 1987.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 11-station dialysis facility by relocating 11 stations from Catawba County Dialysis.

Patient Origin

On page 107, the 2026 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 Catawba 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 Catawba County Dialysis as part of this proposal:

Catawba County Dialysis Historical Patient Origin						
Last Full FY						
CY 2025						
County	# IC Patients	% Total	# HH Patients	% Total	# PD Patients	% Total
Catawba	35	68.6%	4	66.67%	19	52.78%
Alexander	1	2.0%	1	16.67%	0	0.00%
Burke	4	7.8%	0	0.00%	5	13.89%
Cleveland	2	3.9%	0	0.00%	2	5.56%
Iredell	1	2.0%	0	0.00%	0	0.00%
Caldwell	5	9.8%	0	0.00%	8	22.22%
Lincoln	1	2.0%	1	16.67%	2	5.56%
Rutherford	1	2.0%	0	0.00%	0	0.00%
Other States	1	2.0%	0	0.00%	0	0.00%
Total	51	100.0%	6	100.0%	36	100.0%

Source: Section C, page 22

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

Newton Dialysis Historical Patient Origin						
Last Full FY						
CY 2029						
County	# IC Patients	% Total	# HH Patients	% Total	# PD Patients	% Total
Catawba	27.58	82.1%	0.0	0.0	0.0	0.0
Alexander	1	3.0%	0.0	0.0	0.0	0.0
Burke	3	8.9%	0.0	0.0	0.0	0.0
Cleveland	1	3.0%	0.0	0.0	0.0	0.0
Iredell	1	3.0%	0.0	0.0	0.0	0.0
Total	33.58	100.0%	0.00%	0.00%	0.00%	0.00%

Source: Section C, page 22

In Section C, pages 22-24, 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-six (26) in-center patients who currently receive their dialysis treatments DaVita-operated facilities in Catawba County and who live in Catawba County and have signed letters indicating they would consider transfer to Newton Dialysis. Also, six (6) patients currently receiving dialysis treatments at the applicant’s Alexander, Burke, Cleveland, and Iredell County facilities have signed letters indicating they would consider transferring to Newton Dialysis. Copies of these letters are provided in Exhibit C-3.

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

ZIP Code of Patient Residence	Catawba County Dialysis
28681 (Alexander)	1
28612 (Burke)	3
28168 (Catawba)	4
28601 (Catawba)	10
28602 (Catawba)	9
28613 (Catawba)	1
28658 (Catawba)	2
28020 (Cleveland)	1
28625 (Iredell)	1
Total	32

Source: Application, page 23

In Section Q, page 85, the applicant utilizes a 3.0% growth rate for patients to be served at the proposed new facility (Newton Dialysis). This growth rate is based on the applicant’s experience operating dialysis facilities in the proposed service area. The applicant provides a 5-Year Average Annual Change Rate (5YAACR) based on its in-center hemodialysis dialysis (ICHHD) patient census at Catawba County Dialysis, as shown in the table below.

Catawba County Dialysis Operating Year Ending	ICHD Patient Census	Growth Rate
12/31/2021	39	
12/31/2022	44	12.8%
12/31/2023	47	6.8%
12/31/2024	56	19.1%
12/31/2025	51	-8.9%
5 Year Average Annual Change Rate (5YAACR)		7.5%

Source: Section Q, page 86

Analysis of Need

In Section C, pages 25-26, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below.

“After a recent analysis of the patients that are served by DaVita in Catawba County, it was determined that DaVita is serving at least thirty-two in-center patients who live in or near the central part of Catawba County. DaVita’s only facility in Catawba is in the northwest part of the county... Thirty-two 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. 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.”

The information is reasonable and adequately supported because Exhibit C.3 documents the 31 in-center patients who are interested in transferring their care to the proposed facility, located in central Catawba County, and that the new facility will be more convenient for them.

Projected Utilization

In Section Q, Form C, pages 86-89, the applicant provides projected utilization, as illustrated in the following table.

	IC Stations	IC Patients
The applicant begins with 31 patients dialyzing on 11 stations at the facility as of 01/01/2028.	11	31
The facility’s Catawba County patient census is projected forward a year to 12/31/2028.		$26 \times 1.030 = 26.780$
The patients from outside Catawba County are added. This is the census at the end of FY1.		$26.78 + 6 = 32.78$
The facility’s Catawba County patient census is projected forward a year to 12/31/2029.		$26.78 \times 1.030 = 27.583$
The patients from outside Catawba County are added. This is the census at the end of FY2.		$27.58 + 6 = 33.58$

Source: Section Q, page 86

The following are the in-center patient projections for the proposed dialysis facility using Catawba County’s 3% growth rate for the past five years, based on the applicant’s experience

operating dialysis facilities in the proposed service area. The period of the growth begins January 1, 2028, and is calculated forward to December 31, 2029.

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

- 33 patients / 11 certified stations = 3.0 patients / station
- $3.0 / 4 = .75$ or 75% utilization rate

By the end of FY2, Newton Dialysis is projected to have:

- 34 patients / 11 certified stations = 3.09 patients / station
- $3.09 / 4 = .772$ or 77.2% utilization rate

The projected utilization of 3.0 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 Newton Dialysis facility.
- The applicant's projected utilization in the first two years of operation is based on the applicant's experience operating dialysis facilities in Catawba County.

Access to Medically Underserved Groups

In Section C, page 28, 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	92.2%
Racial and ethnic minorities	39.3%
Women	30.3%
Persons with disabilities	100.0%
Persons 65 and older	49.4%
Medicare beneficiaries	76.5%
Medicaid recipients	15.7%

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
- Written comments
- Responses to comments

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 11-station dialysis facility by relocating 11 stations from Catawba County Dialysis.

In Section D, page 34-36, 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.

Catawba County Dialysis

In Section D, page 34, the applicant provides the following table.

Catawba County Dialysis Center	
County where the facility is located	Catawba
Total number of existing, approved, and proposed dialysis stations as of the application deadline.	21
Number of existing dialysis stations to be reduced, relocated or eliminated in this proposal	11
Total # of dialysis stations upon project completion of this project and all other projects involving this facility.	10

Source: Section D, page 34

In Section D, page 35, the applicant provides a table showing the projected utilization for Catawba County Dialysis through the first two project years, as summarized below.

	ICHD Stations	ICHD Patients
Catawba County Dialysis begins with 51 patients dialyzing on 21 stations at the facility as of 01/01/2026.	21	$35 + 16 = 51$
The facility's Catawba County patient census is projected forward a year.		$35 \times 1.075 = 37.613$
The patients from outside Catawba County are added to the facility's census. This is the ending census as of 12/31/2026.		$37.61 + 16 = 53.61$
The facility's Catawba County patient census is projected forward a year.		$36.71 \times 1.075 = 40.420$
The patients from outside Catawba County are added to the facility's census. This is the ending census as of 12/31/2027.		$40.42 + 16 = 56.42$
Newton Dialysis is projected to be certified on 01/01/2028 <ul style="list-style-type: none"> • Eleven stations are projected to transfer to Newton Dialysis from Catawba County Dialysis. • Twenty-six Catawba County patients are projected to transfer out • Six patients from outside of Catawba County are projected to transfer out 	$21 - 11 = 10$	$40.42 - 26 = 14.42$ $16 - 6 = 10$
This is the station count and in-center census on 01/01/2028.	10	$14.42 + 10 = 24.42$
The facility's Catawba County patient census is projected forward a year.		$14.42 \times 1.075 = 15.496$
The patients from outside Catawba County are added to the facility's census. This is the ending census as of the end of OY1.		$15.50 + 10 = 25.50$
The facility's Catawba County patient census is projected forward a year.		$15.50 \times 1.075 = 16.654$
The patients from outside Catawba County are added to the facility's census. This is the ending census as of the end of OY2.		$16.65 + 10 = 26.65$

Section D, page 35

- Projections for patient utilization begin with the patient population at Catawba County Dialysis Center as of December 31, 2025, as reported in the 2026 SMFP. There were 51 IC patients at the facility. Of these 51 patients, 35 lived in the service area, Catawba County, and 16 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 to be 7.5% for patients who live in Catawba County.
- The applicant states that 26 Catawba County patients are projected to transfer to Newton Dialysis upon certification.

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

- 26 patients / 10 certified stations = 2.6 patients / station
- $2.6 / 4 = .65$ or 65% utilization rate

On page 35, 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.”

Access to Medically Underserved Groups

The applicant adequately demonstrates that the needs of medically underserved groups that will continue to use dialysis services at Catawba County Dialysis will be adequately met following completion of the project for the following reasons:

- The applicant states that the relocation of stations from Catawba County 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 Catawba County Dialysis by policy will continue to make dialysis services available to all residents its service area without qualifications.
- The applicant states that Catawba County 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
- Written comments
- Responses to comments
- 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 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 11-station dialysis facility by relocating 11 stations from Catawba County Dialysis.

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 maintaining the status quo will not meet the needs of a growing in-center patient population served by DaVita in Catawba County, specifically in the identified region of the service area.
- Locating a facility in another area of Catawba County: The applicant states that the site proposed for the new facility was selected because it will allow improved 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 Catawba 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
- Written comments
- Responses to comments
- 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 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 11-station dialysis facility, Newton Dialysis, by relocating no more than 11 dialysis stations from Catawba County Dialysis.**
 3. **Upon completion of the proposed project, the certificate holder shall take the necessary steps to decertify 11 stations at Catawba County Dialysis for a total of no more than 10 in-center stations upon completion of the project.**
 4. **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 September 1, 2026.**
 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 develop a new 11-station dialysis facility by relocating 11 stations from Catawba County 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	\$61,510
Construction Costs	\$1,528,594
Architect/Engineering Fees	\$69,020
Medical Equipment	\$183,790
Non-Medical Equipment	\$606,292
Furniture	\$86,580
Interest during Construction	\$72,941
Total	\$2,608,727

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 42-43, the applicant projects that start-up costs will be \$169,012 and initial operating expenses will be \$567,307 for a total working capital of \$736,319. On page 43, 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 41, the applicant states that the capital cost will be funded by accumulated reserves. Exhibit F-2c contains a letter dated December 29, 2025, from Chief Accounting Officer of DaVita Kidney Care committing \$3,345,046 for the capital cost and total working capital of the proposed project. In Exhibit F.2, the applicant provides balance sheets for DaVita Inc., which shows that as of December 2025, 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.

Newton Dialysis	CY2028	CY2029
Total Treatments *	4,800	4,918
Total Gross Revenues (Charges)	\$1,258,969	\$1,289,742
Total Net Revenue	\$1,177,606	\$1,206,390
Average Net Revenue per Treatment	\$262	\$262
Total Operating Expenses (Costs)	\$1,134,614	\$1,160,799
Average Operating Expense per Treatment	\$245	\$245
Net Income	\$42,991	\$45,590

Source: Section Q, Form C

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 11-station dialysis facility by relocating 11 stations from Catawba County Dialysis.

On page 107, the 2026 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 Catawba County. Facilities may also serve residents of counties not included in their service area.

According to Table 9A on page 114 of the 2026 SMFP, there are five existing or approved dialysis facilities in Catawba County as shown in the following table:

Catawba County			
Facility	Certified stations of 12/31/2024	# of IC Patients 12/31/2024	Utilization by% as of 12/31/2024
Catawba County Dialysis	21	56	66.67%
FMC Dialysis Services of Hickory	33	95	71.97%
FMC of Catawba Valley	25	76	76.00%
Fresenius Kidney Care Newton	17	41	60.29%
Fresenius Kidney Care North Catawba	0	0	0.00%

Source: Table 9A of the 2026 SMFP

In Section G, page 48, the applicant explains why it believes its proposal would not result in the necessary duplication of existing or approved dialysis services in Catawba County. The applicant states:

“This certificate of need application does not propose to increase the number of stations in Catawba County. Transferring ten (10) stations from Catawba County 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 Catawba County.
- The applicant adequately demonstrates that the proposed relocation of the existing certified dialysis stations is needed in Catawba 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 11-station dialysis facility by relocating 11 stations from Catawba County 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
	CY2028	CY2029
Administrator	1.00	1.00
Registered Nurses (RNs)	1.50	1.50
Technicians (PCT)	4.25	4.25
Dietician	0.50	0.50
Social Worker	0.50	0.50
Administration /Business Office	0.50	0.50
Other Biomedical Tech	0.50	0.50
Total	8.75	8.75

Source: Section Q, Form H

The assumptions and methodology used to project staffing are provided following Form H in Section Q, page 99. 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, 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 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 11-station dialysis facility by relocating 11 stations from Catawba County Dialysis.

Ancillary and Support Services

In Section I, page 54, the applicant identifies the necessary ancillary and support services for the proposed services. In Section I, 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.

Coordination

In Section I, page 56, 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 and provides supporting documentation in Exhibit I.2.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

- 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.

- (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 11-station dialysis facility by relocating 11 stations from Catawba County Dialysis.

In Section K, page 61, the applicant states that the project involves constructing approximately 6,350 square feet of new space. Line drawings are provided in Exhibit K-2.

In Section K, pages 61, 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 at least 11 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 62, 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 62-63, 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 67, the applicant provides the historical payor mix during CY2025 for its existing services at Catawba County Dialysis, as shown in the table below.

Payor Source	Catawba County Dialysis Last Full FY 01/01/2025 to 12/31/2025					
	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*	1	2.0%	0	0.0%	6	16.7%
Medicare*	39	76.5%	6	100.0%	26	72.2%
Medicaid*	8	15.7%	0	0.0%	1	2.8%
Other-VA	3	5.9%	0	0.0%	3	8.3%
Total	51	100.0%	6	100.0%	36	100.0%

In Section L, page 68, the applicant provides the following comparison.

Last Full FY Submission of the Application		
Catawba County Dialysis	Percentage of Total Patients	Percentage of the Population of the Service Area
Female	30.0%	12.3%
Male	69.7%	87.7%
Unknown	0.0%	0.0%
64 and Younger	50.6%	80.6%
65 and Older	49.4%	19.4%
American Indian	0.0%	0.7%
Asian	7.9%	5.0%
Black or African American	19.1%	9.0%
Native Hawaiian or Pacific Islander	0.0%	0.2%
White or Caucasian	60.7%	72.1%
Other Race	12.4%	2.4%
Declined/ Unavailable	NA	NA

Source: Section L, page 68

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 68, the applicant states it has no such obligation.

In Section L, page 68, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights equal access complaints have been filed against Catawba County Dialysis Center.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section L, page 69, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

Newton Dialysis Projected Payor Mix during the 2nd Full FY 01/01/2029 to 12/31/2029		
Payor Source	In-center Dialysis	
	# of Patients	% of Total
Self-Pay	0.00	0.0%
Insurance*	0.66	2.0%

Medicare*	25.68	76.5%
Medicaid*	5.27	15.7%
Other-VA	1.98	5.9%
Total	33.58	100.0%

Source: Section L, page 69

As shown in the table above, during the second full fiscal year of operation, the applicant projects 76.5% of services will be provided to Medicare patients; and 15.7% of services will be provided to Medicaid patients.

On page 69, the applicant provides the assumptions and methodology it uses to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical experience of the applicant's existing dialysis facility in the proposed service area.

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 L5.

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 11-station dialysis facility by relocating 11 stations from Catawba County Dialysis.

In Section M, page 72, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.1. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the applicant provides a copy of a letter sent to Catawba Valley 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 11-station dialysis facility by relocating 11 stations from Catawba County Dialysis.

On page 107, the 2026 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 Catawba County. Facilities may also serve residents of counties not included in their service area.

According to Table 9A on page 114 of the 2026 SMFP, there are five existing or approved dialysis facilities in Catawba County as shown in the following table:

Catawba County			
Facility	Certified stations of 12/31/2024	# of IC Patients 12/31/2024	Utilization by% as of 12/31/2024
Catawba County Dialysis	21	56	66.67%
FMC Dialysis Services of Hickory	33	95	71.97%
FMC of Catawba Valley	25	76	76.00%
Fresenius Kidney Care Newton	17	41	60.29%
Fresenius Kidney Care North Catawba	0	0	0.00%

Source: Table 9A of the 2026 SMFP

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

“The development of Newton 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.”

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 74, 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 74, the applicant states:

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

See also 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
- Written comments
- Responses to comments
- 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

The applicant proposes to develop a new 11-station dialysis facility by relocating 11 stations from Catawba County 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 104 existing or approved kidney disease treatment facilities located in North Carolina.

In Section O, page 79, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents resulting in an Immediate jeopardy violation that occurred in any of these facilities. After reviewing and considering information provided by the applicant and publicly available data considering the quality of care provided at all 104 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 Q, page 86, the applicant projects 33 in-center patients will be served by the proposed facility by the end of the first operating year, FY 2028 for utilization rate of 3.0 patients per station per week or 75.0% (33 patients / 11 stations = 3.0 patients per station / 4 = 0.75) The projected utilization of 3.0 patients per station per week exceeds the 2.8 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 23-24, 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.