

+REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: June 25, 2026

Findings Date: June 25, 2026

Project Analyst: Crystal Kearney

Co-Signers: Ena Lightbourne

Lisa Pittman

Project ID #: A-12764-26

Facility: Smoky Mountain Dialysis Center

FID #: 050254

County: Cherokee

Applicant(s): Total Renal Care of North Carolina, LLC

Project: Add no more than three in-center dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 16 in-center dialysis 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 three dialysis station at Smoky Mountain Dialysis Center pursuant to Condition 2 of the facility need methodology for a total of no more than 16 stations upon project completion.

Need Determination (Condition 2)

Chapter 9 of the 2026 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table 9B, on page 127 of the 2026 SMFP, the county need methodology

shows there is not a county need determination for additional dialysis stations in Cherokee County.

However, the applicant is eligible to apply for additional dialysis stations in an existing facility pursuant to Condition 2 of the facility need methodology in the 2026 SMFP, if the utilization rate for the facility as reported in the 2026 SMFP is at least 75 percent or 3.0 patients per station per week or greater, as stated in Condition 2.a. The utilization rate reported for the facility in Table 9A, page 114 of the 2026 SMFP, is 80.77% or 3.23 patients per station per week, based on 42 in-center dialysis patients and 13 certified dialysis stations ($42 \text{ patients} / 13 \text{ stations} = 3.2308$, $3.23 / 4 = 80.77\%$).

As shown in Table 9D, on page 132 of the 2026 SMFP, based on the facility need methodology for dialysis stations, the potential number of stations needed is up to five additional stations; thus, the applicant is eligible to apply to add up to five stations during the 2026 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than three new stations to the facility, which is consistent with the 2026 SMFP calculated facility need determination for up to five stations; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

Policies

One policy in Chapter 4 of the 2026 SMFP is applicable to this review, *Policy GEN-5: Access to Culturally Competent Healthcare*.

Policy GEN-5, pages 30-31 of the 2026 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.”

Demographics

In Section B, page 21, the applicant provided the following table that reflects the patient demographics at Smoky Mountain Dialysis Center.

Group	Last Full FY before Submission of the Application	
	Percentage of Total Patients Served	Percentage of the Population of the Service Area
a. Low-income persons	84.8%	15.4%
b. Racial and ethnic minorities	15.4%	7.2%
c. Women	50.0%	50.8%
d. Persons with disabilities	100.0%	12.0%
e. Persons 65 and older	34.6%	32.8%
f. Medicare beneficiaries	78.3%	n/a
g. Medicaid recipients	6.5%	n/a
h. Language: English	96.2%	96.6%
i. Language: Other	3.8%	3.4%
j. High school graduate or higher	n/a	92.2%
k. Percent of population – Urban*	n/a	0.00%
l. Percent of population – Rural*	n/a	100.0%

*County-level Urban and Rural information for the 2020 Census (Updated September 2023),
<https://www.census.gov/programs-surveys/geography/guidance/geo-areas/urban-rural.html>

The applicant states the health equity is foundational to achieving DaVita’s vision of an *unwavering pursuit of a healthier tomorrow*. The applicant states that DaVita’s 2024 Community Care Annual Report is the annual report outlining our overall approach to our

Environmental, Social and Governance (ESG) goals. On page 20, the applicant states, *“We are committed to enabling equity for all patients at every step of the kidney care journey. This means reducing and eliminating barriers so that ALL of our patients are empowered to achieve their optimal kidney health, regardless of race, socio-economic status, gender or other social drivers. Culturally competent care is essential as we strive towards health equity.”*

In Section B, pages 21-22, the applicant adequately describes the strategies it would implement to provide culturally competent services to members of the medically underserved community it identified in the table above and how progress will be assessed. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will provide culturally competent services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant does not propose to develop more dialysis stations than are determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with *Policy GEN-5* based on the following:
 - The applicant provided patient demographics for Cherokee County.
 - The applicant described the strategies that it would implement at Smoky Mountain Dialysis including offering language assistance services to patients that have limited English proficiency and providing Health Equity and Cultural Humility training to all teammates.
 - The applicant described how its strategies reflect cultural competence because the plan meets patients where they are and individualizes their care and it helps teammates develop a set of skills and knowledge to better understand the importance of respecting patients’ different perspectives.
 - The applicant described how it will measure and periodically assess increased equitable access to healthcare services and reduction in health disparities, including assessing data and performance for different patient populations and reviewing the data and plan annually.

(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 three dialysis stations at Smoky Mountain Dialysis Center pursuant to Condition 2 of the facility need methodology for a total of no more than 16 dialysis stations upon project completion.

Patient Origin

On page 107, the 2026 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.”* Thus, the service area for this facility consists of Cherokee County. Facilities may also serve residents of counties not included in their service area.

The following tables illustrate historical and projected patient origin.

Smoky Mountain Dialysis Center Last Full FY 1/1/2025 to 12/31/2025						
County	# of in-center Patients	% of Total	# of Home Hemodialysis Patients **	% of Total	# of Peritoneal Dialysis Patients**	% of Total
Cherokee	21	45.7%			8	61.54%
Carteret	1	2.2%				0.00%
Clay	4	8.7%			2	15.38%
Graham	3	6.5%			2	15.38%
Wake	1	2.2%				0.00%
Georgia	10	21.7%			1	7.69%
Tennessee	2	4.3%				0.00%
Other States	4	8.7%				0.00%
Total	46	100.0%	0		13	100.00%

Source: Section C, page 24.

Smoky Mountain Dialysis Center Second Full FY 1/1/2029 to 12/31/2029						
County	# of in-center Patients	% of Total	# of Home Hemodialysis Patients **	% of Total	# of Peritoneal Dialysis Patients* *	% of Total
Cherokee	27.5267	52.4%			12	70.59%
Carteret	1	1.9%				
Clay	4	7.6%			2	11.76%
Graham	3	5.7%			2	11.76%
Wake	1	1.9%				
Georgia	10	19.0%			1	5.88%
Tennessee	2	3.8%				
Other States	4	7.6%				
Total	52.5267	100.0%	0		17	100.00%

Source: Section C, page 25

In Section C, pages 25-26, the applicant provides the assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported based on the following:

- The applicant began projections for patient utilization with the patient population at Smoky Mountain Dialysis Center as of December 31, 2025. The facility had 46 patients and 21 of those patients lived in the Cherokee County service area. The remaining 25 patients lived outside the service area.
- The applicant used the 7.0% Average Annual Change Rate for the Past Five Years (5YAACR) for the in-center patients living in Cherokee County. The period of growth begins January 1, 2026, and is calculated forward to December 31, 2028.
- The applicant did not calculate growth for the patients living outside of Cherokee County.

Analysis of Need

In Section C, page 27, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 27, the applicant states:

“There is a facility need determination of 5 stations for Smoky Mountain, which had 13 existing, as reported in Tables 9D and 9A of the 2026 SMFP. ...we demonstrate that an additional 3 stations will be well utilized by the population to be served, this 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 the facility. Dialysis patients spend a significant amount of time in their facilities preparing for and receiving treatment – three times a week for in-center patients. The additional stations provide opportunities to open appointment times on the more desirable first shift.”

The information is reasonable and adequately supported because the applicant demonstrates eligibility to add dialysis stations to its facility under Condition 2 of the facility need methodology, as stated in the 2026 SMFP. The discussion regarding the need methodology found in Criterion (1) is incorporated herein by reference.

Project Utilization

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

Form C Utilization	Last Full FY CY 2025	Interim Full FY CY 2026	Interim Full FY CY 2027	1st Full FY CY 2028	2nd Full FY CY 2029
In-Center Patients					
# of Patients at Beginning of Year	42.00	46.00	47.47	49.04	50.73
# of Patients at the End of the Year	46.00	47.47	49.04	50.73	52.53
Avg. # of Patients During the Year	44.00	46.74	48.26	49.88	51.63
# of Treatments Patient / Year*	133.25	148.20	148.20	148.20	148.20
Total # of Treatments	5,863.00	6,926.13	7,151.61	7,392.87	7,651.02
Peritoneal Dialysis Patients					
# of Patients at Beginning of Year	11.00	13.00	14.00	15.00	16.00
# of Patients at the End of the Year	13.00	14.00	15.00	16.00	17.00
Avg. # of Patients During the Year	12.00	13.50	14.50	15.50	16.50
# of Treatments Patient/Year	488.58	148.20	148.20	148.20	148.20
Total # of Treatments	5,863.00	2,000.70	2,148.90	2,297.10	2,445.30
Total Patients					
# of Patients at the Beginning of the Year	53.00	59.00	61.47	64.04	66.73
# of Patients at the End of the Year	59.00	61.47	64.04	66.73	69.53
Avg. # of Patients during the Year	56.00	60.24	62.76	65.38	68.13
# of Treatments Patients /Year	209.39	148.20	148.20	148.20	148.20
Total # of Treatments	11,726.00	8,926.83	9,300.51	9,689.97	10,096.32

of Treatments / Patient/ Year assumes patient receives treatment 3 times a week, 52 weeks a year and includes a missed treatment rate of 5% ($3 \times 52 \times 0.95 = 148$)

In Section C, pages 25-26, and Section Q, page 85, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The applicant began with the patient census at Smoky Mountain as of December 31, 2025. There were 46 in-center patients and of those 46 patients, 21 patients lived in Cherokee County and 25 lived outside of Cherokee County.
- The applicant used the 7.0% 5YAACR for the Cherokee County in-center patients. No growth was calculated for patients living outside of Cherokee County; however they were added at the appropriate times in the methodology.
- The period of growth begins January 1, 2026, and is calculated forward to December 31, 2028.
- The first full FY is CY 2028, and the second full FY is CY 2029.

	IC Stations	IC Patients
Station count and patient census at the facility as of 12/31/2025.	13	46
The facility's Cherokee County patient census is projected forward a year to 12/31/2026 This is the ending census for the first interim partial year.		$21 \times 1.070 = 22.470$
The patients outside of Cherokee County are added. This is the ending census for the first interim full year.		$22.47 + 25 = 47.47$
The facility's Cherokee County patient census is projected forward a year to 12/31/2027.		$22.47 \times 1.070 = 24.04290$
The patients outside of Cherokee County are added. This is the ending census for the second interim full year.		$24.04 + 25 = 49.04$
The proposed project is projected to be certified on 1/1/2028. This is the station count at the beginning of the project's first full fiscal year (FY1). The facility's Cherokee County patient census is projected forward a year to 12/31/2028	$13 + 3 = 16$	$24.04 \times 1.070 = 25.72590$
The patients from outside Cherokee County are added. This is the ending census for the first full fiscal year (FY1).		$25.73 + 25 = 50.73$
The facility's Cherokee County patient census is projected forward a year to 12/31/2029.		$25.73 \times 1.070 = 27.52672$
The patients outside of Cherokee County are added. This is the ending census for the second full fiscal year (FY2).		$25.73 + 25 = 52.53$

Source: Section C, page 26 of the application

- Projected patients for FY1 and FY2 are rounded to the nearest whole number.
Based on the calculations above, by the end of FY1 Smoky Mountain is projected to have:
 - $51 \text{ patients} / 16 \text{ certified stations} = 3.188 \text{ patients} / \text{station}$
 - $3.188 / 4 = 0.796875$ or 79.69% utilization rate

Projected Utilization for Training and Support Services		
	# of Home Hemodialysis Patients Trained*	# of Peritoneal Dialysis Patients Trained*
Last Full FY		6
Interim Full FY		7
Interim Full FY		8
1 st Full FY of Operation		9
2 nd Full FY of Operation		10

Source: Section C, page 29 of the application

In Section C, page 29 the Applicant states:

“It is important to note that not all patients who are trained to perform home dialysis stay on the modality. There are a variety of reasons why a patient may begin but not complete training or may not continue dialyzing at home after they do. These reasons include receiving a transplant, a medically necessary modality change, and patient choice to name a few. Therefore, the total number of home patients trained in a year is not interchangeable with the total number of patients performing their hemodialysis or peritoneal dialysis in a location other than the dialysis facility, as reflected in the patient census reported at the end of the year.”

Six PD patients were trained at Smoky Mountain last year. The following projections for home training patient utilization assume:

- at least 6 PD patients will be trained in the first full year of operation.
- the total number of patients trained in the home-training program at the facility will grow at a rate of at least one training patient per year during the period of growth.

	# of PD Patients Trained
The total number of patients trained in home modalities last FY.	6
The total number of home patients trained at the facility is projected forward a year to 12/31/2026. This is the total number of home patients trained in Interim Year 1.	$6 + 1 = 7$
The total number of home patients trained at the facility is projected forward a year to 12/31/2027. This is the total number of home patients trained in Interim Year 2.	$7 + 1 = 8$
The total number of home patients trained at the facility is projected forward a year to 12/31/2028. This is the total number of home patients trained in FY1.	$8 + 1 = 9$
The total number of home patients trained at the facility is projected forward a year to 12/31/2029. This is the total number of home patients trained in FY2.	$9 + 1 = 10$

Source: Section C, page 30 of the application

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

- The applicant projects future utilization based on historical utilization and growth.
- Projected utilization at the end of FY1 meets the minimum of 2.8 patients per station per week as required by 10A NCAC 14C .2203(b).
- Projected utilization for home patient projections assume that the facility's home census will grow at a rate of at least one patient per year per modality during the period of growth.

Access to Medically Underserved Groups

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

“By policy, the proposed services will be made available to all residents in the service area without qualifications. The facility will serve patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability and socioeconomic groups of patients in need of dialysis.

We will make every reasonable effort to accommodate all patients, especially those with special needs such as those with disabilities, patients attending school or patients who work. Dialysis services will be provided six days per week with two patient shifts per day to accommodate patient need.

Smoky Mountain 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.”

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

Medically Underserved Groups	Percentage of Total Patients during the Second Full Fiscal Year
Low income persons	84.8%
Racial and ethnic minorities	15.4%
Women	50.0%
Persons with Disabilities	100.0%
Persons 65 and older	34.6%
Medicare beneficiaries	78.3%
Medicaid recipients	6.5%

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose to reduce a service, eliminate a service or relocate a facility or 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 three dialysis stations at Smoky Mountain Dialysis Center pursuant to Condition 2 of the facility need methodology for a total of no more than 16 dialysis stations upon project completion.

In Section E, page 40, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- **Maintain the status quo.** The applicant determined that this was a less effective alternative due to the growth rate at Smoky Mountain Dialysis Center.
- **Develop more stations.** The applicant states that the physical plant can currently accommodate 16 in-center stations without costly renovations.

In Section C, page 27, the applicant determined that its proposal is the most effective alternative because the additional station will increase capacity and proactively address the issues of growth and access at Smoky Mountain Dialysis Center and provide opportunities to open appointment times on the more desirable first shift.

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 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 2 of the facility need determination in the 2026 SMFP, the certificate holder shall develop no more than 3 additional in-center dialysis station for a total of no more than 16 in-center stations at Smoky Mountain Dialysis Center upon completion of this project.**
- 3. Progress Reports:**
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. The certificate holder shall complete all sections of the Progress Report form.**
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. The first progress report shall be due on December 1, 2026.**
- 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 three dialysis stations at Smoky Mountain Dialysis Center pursuant to Condition 2 of the facility need methodology for a total of no more than 16 dialysis stations upon project completion.

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.

Capital Cost	
Medical Equipment	\$40,500
Non Medical Equipment	\$14,500
Furniture	\$6,000
Total	\$61,000

In Section Q, page 89, 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 because Davita's Project Manager for North Carolina and Finance used a corporate model and regional database along with inputs from operations and the regional Real Estate team to develop the capital cost for the proposed project.

In Section F, page 43, the applicant states that there will be no start-up costs or initial operating expenses because Smokey Mountain Dialysis Center is an existing facility and its revenues exceed its operating costs.

Availability of Funds

In Section F, page 42, the applicant states that the capital cost will be funded with Total Renal Care of North Carolina, LLC's accumulated reserves.

Exhibit F.2c contains a letter dated March 6, 2026, from the Chief Accounting Officer at DaVita Kidney Care. DaVita is the parent company and 100% owner of Total Renal Care, Inc., which owns 85% of the ownership interest in Total Renal Care of North Carolina, LLC. The letter confirmed that DaVita is willing to commit cash reserves for the capital costs of the proposed project.

Exhibit F.2 contains DaVita Inc.'s Consolidated Balance Sheet for the years ending December 31, 2024, and December 31, 2025. According to the Consolidated Balance Sheet, as of

December 31, 2025, DaVita, Inc. had adequate cash and assets to fund all the capital needs of the project.

The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project based on the following:

- The applicant provides a letter from the appropriate Davita Inc. official confirming the availability of the funding proposed for the capital needs of the project and the commitment to use those funds to develop the proposed project.
- The applicant provides adequate documentation of the accumulated reserves it proposes to use to fund 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, in Section Q, the applicant projects that revenues will exceed operating expenses in the first two full fiscal years following completion of the project, as shown in the table below.

	1st Full Fiscal Year CY 2028	2nd Full Fiscal Year CY 2029
Total # of Treatments	9,690	10,096
Total Gross Revenues (Charges)	\$2,949,730	\$3,069,864
Total Net Revenue	\$2,759,604	\$2,871,765
Average Net Revenue per Treatment	\$285	\$285
Total Operating Expenses (Costs)	\$2,441,816	\$2,511,358
Average Operating Expense per Treatment	\$252	\$249
Net Income	\$317,788	\$360,407

The assumptions used by the applicant in preparation of the pro forma financial statements are provided 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 including projected reimbursement rates by payor source and operating cost 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 needs 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 three dialysis stations at Smoky Mountain Dialysis Center pursuant to Condition 2 of the facility need methodology for a total of no more than 16 dialysis stations upon project completion.

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.*” Smoky Mountain Dialysis Center is in Cherokee County. Thus, the service area for this facility is Cherokee County. Facilities may serve residents of counties not included in their service area.

According to the 2026 SMFP, Table 9A, page 114, there is one existing or approved dialysis facility in Cherokee County, as shown in the following table:

	# of Certified Stations as of 12/31/2024	# of In-Center Patients as of 12/31/2024	Utilization Rate as of 12/31/2024	Patients per Station as of 12/31/2024
Smoky Mountain Dialysis Center	13	42	80.77%	3.231

Source: Section G, page 49 of the application

In Section G, page 49, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or dialysis services in Cherokee County. The applicant states:

“Based on the facility need methodology in the 2025 SMFP under Condition 2, Smoky Mountain qualifies to add up to 5 dialysis stations.

...While adding stations at this facility does increase the number of stations in Cherokee 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:

- There is a facility need determination in the 2026 SMFP for up to five dialysis stations at Smoky Mountain.
- The applicant adequately demonstrates that the proposed dialysis stations are needed in addition to the existing or approved dialysis stations in Cherokee 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 add no more than three dialysis stations at Smoky Mountain Dialysis Center pursuant to Condition 2 of the facility need methodology for a total of no more than 16 dialysis 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 2/28/2026	2nd Full Fiscal Year CY 2029
Administrator	1.00	1.00
Registered Nurses (RNs)	1.75	2.00
Home Training Nurse	0.50	0.50
Technicians (PCT)	5.00	6.00
Dietician	0.50	0.50
Social Worker	0.50	0.50
Administration/Business Office	1.00	1.00
Other - Biomedical Tech	0.50	0.50
TOTAL	10.75	12.00

The assumptions and methodology used to project staffing are provided in Section Q, page 97. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Section Q, Form F.4. In Section H, pages 52-53, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

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

- The facility is an existing facility, and the applicant bases its staffing on its historical experience providing dialysis services at the facility.
- The applicant has existing resources to recruit or fill vacant or new positions, train staff, and provide continuing education.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to add no more than three dialysis stations at Smoky Mountain Dialysis Center pursuant to Condition 2 of the facility need methodology for a total of no more than 16 dialysis stations upon project completion.

Ancillary and Support Services

In Section I, page 55, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 55-57, the applicant explains how each ancillary and support service is or will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available.

Coordination

In Section I, page 57, the applicant describes its existing 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 its established relationships with other healthcare providers and social service agencies in Cherokee 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.

- (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 67, the applicant provides the historical payor mix during CY 2025 for the proposed services, as shown in the table below.

Smoky Mountain Dialysis Center						
Last Full FY						
CY 2025						
	In-center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
Primary Payor Source at Admission	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Insurance *	3	6.5%			0	0.0%
Medicare*	36	78.3%			11	84.6%
Medicaid*	3	6.5%			1	7.7%
Other-VA	4	8.7%			1	7.7%
Total	46	100.0%	0		13	100.0%

Source: Section L, page 67

*Including any managed care plans

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

Smoky Mountain Dialysis Center		
Last Full FY before Submission of the Application		
	% of Total Patients Served ^	% of the Population of the Service Area*
Female	50.0%	50.8%
Male	50.0%	49.2%
64 and Younger	65.4%	67.2%
65 and Older	34.6%	32.8%
American Indian	7.7%	1.8%
Asian	0.0%	0.7%
Black or African-American	1.9%	1.9%
Native Hawaiian or Pacific Islander	1.9%	0.1%
White or Caucasian	84.6%	92.8%
Other Race	3.8%	2.7%

Source: Section L, page 68 of the application

^All patients (in-center, home hemodialysis, and peritoneal dialysis).

*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

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 obligation to provide uncompensated care , community service, or access by minorities and persons with disabilities.

In Section L, page 68, 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 or any similar facilities owned by the applicant or a related entity and located in North Carolina.

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

Smoky Mountain Dialysis Center Projected Payor Mix during the 2 nd Full FY CY 2029						
Payor Source	In-center Dialysis		Home Hemodialysis**		Peritoneal Dialysis **	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Insurance *	3.43	6.5%			0.00	0.0%
Medicare*	41.11	78.3%			14.38	84.6%
Medicaid*	3.43	6.5%			1.31	7.7%
Other-VA	4.57	8.7%			1.31	7.7%
Total	52.53	100.0%	0	0.0%	17.00	100.0%

*Including any managed care plans

Source: Section L, page 69 of the application

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 6.5% of total in-center services will be provided to self-pay patients, 78.3% to Medicare patients and 6.5% to Medicaid patients.

On page 69, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical payor mix at Smoky Mountain Dialysis Center during the last full fiscal year (CY2025).

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

- (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 three dialysis stations at Smoky Mountain Dialysis Center pursuant to Condition 2 of the facility need methodology for a total of no more than 16 dialysis stations upon project completion.

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's statement that it has offered the facility as a clinical learning site for nursing students from Tri-County Community College and providing a copy of the letter sent to Tri-County Community College in Exhibit M.1.

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 three dialysis stations at Smoky Mountain Dialysis Center pursuant to Condition 2 of the facility need methodology for a total of no more than 16 dialysis stations upon project completion.

On page 107, the 2026 SMFP defines the service area 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.*” Smoking Mountain Dialysis Center is in Cherokee County. Thus, the service area for this facility is Cherokee County. Facilities may serve residents of counties not included in their service area.

According to the 2026 SMFP, Table 9A, page 114, there is one existing or approved dialysis facility in Cherokee County, as shown in the following table:

Cherokee County			
	# of Certified Stations as of 12/31/2024	# of In-Center Patients as of 12/31/2024	Utilization Rate as of 12/31/2024
Smoking Mountain Dialysis Center	13	42	80.77%

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

“The expansion of Smoky Mountain will have no effect on competition in Cherokee County. There are no other dialysis facilities in this Multicounty Planning Area; therefore, there can be no effect on the competition.

...

The expansion of Smoky Mountain will enhance accessibility to dialysis for our patients, and by reducing the economic and physical burdens on our patients, this project will enhance the quality and cost effectiveness of our services because it will make it easier for patients, family members and others involved in the dialysis process to receive services.”

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

“The expansion of Smoky Mountain will enhance accessibility to dialysis for current and projected patients and, by reducing the economic and physical burdens on our patients, this project will enhance the quality and cost effectiveness of our services because it will make it easier for patients, family members and others involved in the dialysis process to receive services. . As noted in Form H, with additional capacity, greater operational efficiency is possible which positively impacts cost-effectiveness. As discussed in Section B and Section O, DaVita is committed to providing quality care to the ESRD population and, by policy, works to make every reasonable effort to accommodate all of its patients.’

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

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

“The expansion of Smoky Mountain will enhance accessibility to dialysis for current and projected patients and, by reducing the economic and physical burdens on our patients, this project will enhance the quality and cost effectiveness of our services because it will make it easier for patients, family members and others involved in the dialysis process to receive services. . As noted in Form H, with additional capacity, greater operational efficiency is possible which positively impacts cost-effectiveness. As discussed in Section B and Section O, DaVita is committed to providing quality care to the ESRD population and, by policy, works to make every reasonable effort to accommodate all of its patients.’

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 74, the applicant states:

“.... 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 and B, C of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive

impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

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 104 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, there were no incidents resulting in a finding of immediate jeopardy that occurred in any of these facilities. After reviewing and considering information provided by the applicant and considering the quality of care provided at all 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.

10 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.*
- NA- Smoky Mountain Dialysis Center 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 26, and on Form C in Section Q, the applicant projects to serve 51 in-center patients on 16 stations, or a rate of 3.19 in-center patients per station per week (51 patients / 16 stations = 3.19), by the end of the first operating year following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- (c) *An applicant proposing to establish a new dialysis facility dedicated to home hemodialysis or peritoneal dialysis training shall document the need for the total number of home hemodialysis stations in the facility based on training six home hemodialysis patients per station per year as of the end of the first full fiscal year of operation following certification of the facility.*
- NA- The applicant does not propose to establish a new dialysis facility dedicated to home hemodialysis or peritoneal dialysis training. Therefore, this Rule does not apply.

- (d) *An applicant proposing to increase the number of home hemodialysis stations in a dialysis facility dedicated to home hemodialysis or peritoneal dialysis training shall document the need for the total number of home hemodialysis stations in the facility based on training six home hemodialysis patients per station per year as of the end of the first full fiscal year of operation following certification of the additional stations.*
- NA- The applicant does not propose to increase the number of home hemodialysis stations. Therefore, this Rule does not apply.
- (e) *The applicant shall provide the assumptions and methodology used for the projected utilization required by this Rule.*
- C- In Section C, pages 25-26 and pages 29-30, and 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.