

REQUIRED STATE AGENCY FINDINGS

FINDINGSs

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: May 15, 2025

Findings Date: May 15, 2025

Project Analyst: Ena Lightbourne

Co-Signer: Gloria C. Hale

Project ID #: B-12615-25

Facility: Weaverville Dialysis

FID #: 000318

County: Buncombe

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

Project: Add no more than 10 in-center dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 30 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 10 in-center (IC) dialysis stations at Weaverville Dialysis pursuant to Condition 2 of the facility need methodology for a total of no more than 30 in-center stations upon project completion. According to the 2025 ESRD data collection forms, Weaverville Dialysis does not serve peritoneal or home hemodialysis patients as of December 31, 2024.

Need Determination (Condition 2)

Chapter 9 of the 2025 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the 2025 SMFP, Table 9B, page 132, the county need methodology

shows there is no county need determination for additional dialysis stations in Buncombe 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 2025 SMFP, if the utilization rate for the facility as reported in the 2025 SMFP is at least 75 percent or 3.0 patients per station per week, as stated in Condition 2.a. As reported in Table 9A, page 119, the utilization rate for the facility is 86.25% or 3.45 patients per station per week, based on 69 in-center dialysis patients and 20 certified dialysis stations ($69 \text{ patients} / 20 \text{ stations} = 3.45$; $3.45 / 4 = 0.8625$ or 86.25%).

As shown in Table 9D, page 137 of the 2025 SMFP, based on the facility need methodology for dialysis stations, the potential number of stations needed at Weaverville Dialysis is up to 11 additional stations: thus, the applicant is eligible to apply to add up to 11 stations during the 2025 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than 10 new stations to the facility, which is less than the 2025 SMFP calculated facility need determination for up to 11 stations pursuant to Condition 2 of the facility need methodology; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

Policies

There is one policy in the 2025 SMFP that is applicable to this review, Policy *GEN-5: Access to Culturally Competent Healthcare*.

Policy *GEN-5: Access to Culturally Competent Healthcare* states:

A certificate of need (CON) applicant applying to offer or develop a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will provide culturally competent healthcare that integrates principles to increase health equity and reduce health disparities in underserved communities. The delivery of culturally competent healthcare requires the implementation of systems and training to provide responsive, personalized care to individuals with diverse backgrounds, values, beliefs, customs, and languages. A certificate of need applicant shall identify the underserved populations and communities it will serve, including any disparities or unmet needs of either, document its strategies to provide culturally competent programs and services, and articulate how these strategies will reduce existing disparities as well as increase health equity.

CON applications will include the following:

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

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

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

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

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

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

In approving an application, Certificate of Need shall impose a condition requiring the applicant to implement the described strategies in a manner that is consistent with the applicant's representations in its CON application.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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 the following:

- The applicant adequately demonstrates that the application is consistent with the facility need methodology as applied from the 2025 SMFP.
- The applicant adequately demonstrates that the application is consistent with Policy GEN-5 based on:
 - The applicant adequately describes the demographics of Buncombe County, and the demographics of the patient population served at Weaverville Dialysis by providing

patient demographic data, that includes age, racial composition, disability and spoken language.

- The applicant adequately describes its strategies to provide culturally competent services to medically underserved communities. These strategies include offering interpretation and translation services, providing training to all staff on subjects such as health equity, cultural humility, and collecting culturally sensitive demographic information. Additionally, the applicant will implement a process to regularly review health equity data to identify health equity disparities and subsequently develop plans to address these disparities.
- In Exhibit B.8.a, the applicant provides DaVita's 2023 Community Care Annual Report which describes its *Environmental, Social and Governance (ESG)* goals and achievements, particularly in quality care, reduction of health disparities and cultivating a diverse environment in kidney health.
- To support its approach to reduce health disparities and improve health outcomes in medically underserved communities, as described above, in Exhibit B.8.c, the applicant provides the Culturally and Linguistically Appropriate Services (CLAS) action plan for ESRD communities that was developed by the ESRD National Coordinating Center. The action plan was adopted from the CLAS program at the federal level that assists health organizations improve quality of care and eliminate health disparities as communities become more diverse.

(2) Repealed effective July 1, 1987.

(3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to add no more than 10 IC dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 30 IC dialysis stations upon project completion.

On page 113, the 2025 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.*” Weaverville Dialysis is in Buncombe County. Thus, the service area for this facility consists of Buncombe County. Facilities may serve residents of counties not included in their service area.

The following table illustrates historical and projected patient origin.

Weaverville Dialysis Historical and Projected Patient Origin					
Historical			Projected		
01/01/2024-12/31/2024 CY 2024			01/01/2028-12/31/2028 CY 2028 (2nd Project Year)		
County	# of In-Center Patients	% of Total	County	# of In-Center Patients	% of Total
Buncombe	56	80.0%	Buncombe	76	84.5%
Cherokee	2	2.9%	Cherokee	2	2.2%
Henderson	1	1.4%	Henderson	1	1.1%
Madison	8	11.4%	Madison	8	8.9%
Mitchell	1	1.4%	Mitchell	1	1.1%
South Carolina	1	1.4%	South Carolina	1	1.1%
Yancey	1	1.4%	Yancey	1	1.1%
Total	70	100.0%	Total	90	100.0%

Sources: Section C, pages 23-24

In Section C, pages 24-25, and in Section Q, pages 82-83, the applicant provides the assumptions and methodology used to project patient origin. The applicant's assumptions are reasonable and adequately supported because it is based on the historical patient origin for the facility as of December 31, 2024, and the historical 5-year (12/30/2020 – 12/31/2024) Average Annual Change Rate (AACR). The applicant factors in the projected transfer of patients to the facility that reside outside of Buncombe County.

Analysis of Need

In Section C, page 26, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 26, the applicant states:

“There is a facility need determination of 11 stations for Weaverville Dialysis, which had 20 existing stations, as reported on Tables 9D and 9A of the 2025 SMFP...we demonstrate that an additional 10 stations will be well utilized by the population to be served, the current and projected in-center patients of Weaverville Dialysis. The addition of stations serves to increase capacity and proactively address the issues of growth and access at the facility. Dialysis patients spend a significant amount of time in their facilities preparing for and receiving treatment – three times a week for in-center patients. The additional stations provide opportunities to open appointment times on the more desirable first shift.”

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

- The applicant demonstrates eligibility to add dialysis stations to its facility under Condition 2 of the facility need methodology, as stated in the 2025 SMFP. The discussion regarding need methodology found in Criterion (1) is incorporated herein by reference.
- The applicant adequately demonstrates need based on the facility's projected growth in the patient population and maintaining access to dialysis services.

Projected Utilization

In Section C, page 25, and Section Q, page 82, the applicant provides interim and projected utilization, as illustrated in the following table.

Weaverville Dialysis Projected Utilization		
	IC stations	IC patients
Station count and patient census at the facility as of December 31, 2024.	20	70
The facility's Buncombe County patient census is projected forward a year to December 31, 2025. This is the ending census for the first interim partial year.		$56^* \times 1.08 = 60.480$
The patients from outside Buncombe County are added. This is the ending census for the first full interim year.		$60.48 + 14 = 74.48$
The facility's Buncombe County patient census is projected forward a year to December 31, 2026.		$60.48 \times 1.08 = 65.318$
The patients from outside Buncombe County are added. This is the ending census for the second full interim year.		$65.32 + 14 = 79.32$
The proposed project is projected to be certified on January 1, 2027. This is the station count at the beginning of the project's first full fiscal year (FY1).	$20 + 10 = 30$	$65.32 \times 1.08 = 70.544$
The facility's Buncombe County patient census is projected forward a year to December 31, 2027.		
The patients from outside Buncombe County are added. This is the ending census for FY1.		$70.54 + 14 = 84.54$
The facility's Buncombe County patient census is projected forward a year to December 31, 2028.		$70.54 \times 1.08 = 76.187$
The patients from outside Buncombe County are added. This is the ending census of the project's second full fiscal year for (FY2).		$76.19 + 14 = 90.19$

*The 56 IC patients represent 70 patients minus 14 patients from outside of Buncombe County.

In Section C, pages 24-25 and Section Q, pages 82-83, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The applicant projects the first fiscal year of the project will be January 1, 2027 - December 31, 2027, and the second full fiscal year will be January 1, 2028 - December 31, 2028.
- The applicant begins with the patient census as of December 31, 2024, which was 70 IC patients on 20 dialysis stations. Of the 70 patients, 14 resided outside of Buncombe County.
- The applicant grew the Buncombe County patient census using a conservative grow rate of 1.08%, which is significantly lower than the facility's historical 5-year AACR.
- As of December 31, 2024, the facility was serving 14 IC patients residing outside of Buncombe County. The applicant does not project growth for this population and adds these patients to projections of future patient populations at the appropriate time.

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

- FY1: 2.8 patients per station per week or 70.83% (85 patients / 30 stations = 2.833/4 = 0.7083 or 70.83%)
- FY2: 3.0 patients per station per week or 75.00% (90 patients / 30 stations = 3.00 /4 = 0.7500 or 75.00%)

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

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

- The applicant bases projections of the future patient population to be served on the facility census as of December 31, 2024.
- The applicant reasonably projects a growth in the Buncombe County IC patient census through the second year of the project based on a growth rate of 1.08% that is significantly lower than the facility's historical 5-Year AACR.
- The applicant's proposal to add 10 dialysis stations will meet the need of the projected growth of the facility's patient population.
- Projected utilization at the end of OY1 meets the minimum of 2.8 patients per station per week required by 10A NCAC 14C .2203(b).

Access to Medically Underserved Groups

In Section C, page 28, 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.

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

In Section C, page 28, the applicant provides the estimated percentage of total patients to be served for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Estimated Percentage of Total Patients during the Second Full Fiscal Year
Low-income persons	87.1%
Racial and ethnic minorities	14.7%
Women	45.6%
Persons with Disabilities	100.0%
Persons 65 and older	61.8%
Medicare beneficiaries	78.6%
Medicaid recipients	8.6%

Source: Table on page 28 of the application.

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 10 IC dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 30 IC dialysis stations upon project completion.

In Section E, page 37, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo-The applicant states that this alternative was dismissed considering the facility's growth rate. According to the 2025 ESRD data collection forms, the facility had an 87.50% utilization rate as of December 31, 2024.
- Relocate Stations from Another DaVita Facility-The applicant states that relocating stations from the two other Davita-operated facilities in Buncombe County would be a less effective alternative. Arden Dialysis is currently operating above 75% capacity; however, DaVita is planning to apply for additional stations pursuant to the facility need determination in the 2025 SMFP. Furthermore, although Asheville Kidney Center is operating under 75% capacity, DaVita determined that the facility should maintain capacity for displaced patients due to the impact of Hurricane Helene.

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

- The applicant's proposal to add stations to Weaverville Dialysis is based on the facility's eligibility to add stations under Condition 2 of the facility need methodology, as stated in the 2025 SMFP.
- The applicant provides reasonable information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Total Renal Care of North Carolina, LLC. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. Pursuant to Condition 2 of the facility need methodology in the 2025 SMFP, the certificate holder shall add no more than 10 in-center dialysis stations at Weaverville Dialysis for a total of no more than 30 in-center stations upon project completion.**

3. 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.
 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 February 2, 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 add no more than 10 IC dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 30 IC dialysis stations upon project completion.

Capital and Working Capital Costs

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

Capital Costs	
Site Preparation	\$3,300
Construction/Renovation Contracts	\$550,000
Medical Equipment	\$148,500
Non-Medical Equipment	\$42,240
Furniture	\$22,000
Total	\$766,040

In Section Q, page 87, 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.

In Section F, page 40, the applicant states there will be no start-up costs or initial operating expenses because the facility's revenues exceed operating costs.

Availability of Funds

On page 39, the applicant states that the capital cost will be funded through accumulated reserves. The Project Analyst concludes that the applicant is referring to Davita's accumulated reserves based on the supporting documentation provided in the application.

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

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

Financial Feasibility

The applicant provides pro forma financial statements for the first two full operating years following completion of the project. In Form F.2, the applicant projects that revenues will exceed operating expenses in the first two operating years following completion of the project, as shown in the table below.

Weaverville Dialysis	1st Project Year	2nd Project Year
	CY2027	CY2028
Total Treatments	12,142	12,948
Total Gross Revenues (Charges)	\$3,242,486	\$3,457,560
Total Net Revenue	\$3,107,176	\$3,313,275
Average Net Revenue per Treatment	\$256	\$256
Total Operating Expenses (Costs)	\$3,014,078	\$3,132,737
Average Operating Expense per Treatment	\$248	\$242
Net Income	\$93,098	\$180,538

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Forms F.2, F.3 and F.4 in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant adequately explains the assumptions used to project revenue, such as projected reimbursement rates, and operating costs, such as salaries.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
 - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
 - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to add no more than 10 IC dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 30 IC dialysis stations upon project completion.

On page 113, the 2025 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.*” Weaverville Dialysis is in Buncombe County. Thus, the service area for this facility consists of Buncombe County. Facilities may serve residents of counties not included in their service area.

According to 2025 SMFP, Table 9A, page 119, there are four existing or approved dialysis facilities in Buncombe County, as shown in the following table:

Buncombe County					
	Certified Stations as of 12/31/2023*	Number of In-center Patients as of 12/31/2023*	Utilization by Percent as of 12/31/2023*	Patients per Station as of 12/31/2023*	Number of Additional Stations Approved*
Arden Dialysis	14	47	83.93%	3.36	0
Asheville Kidney Center	52	104	50.00%	2.00	-4
Biltmore Home Training	0	0	0.00%	0.00	4
Weaverville Dialysis	20	69	86.25%	3.45	0
Total	86	220	63.95%		

*Source: Table on page 46 of the application and from the 2025 SMFP, Table 9A, page 119.

In Section G, page 46, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Buncombe County. The applicant states:

“Based on the facility need methodology in the 2025 SMFP under Condition 2, Weaverville Dialysis qualifies to add up to 11 dialysis stations.

...we demonstrate the need that Weaverville Dialysis has for adding stations. While adding stations at this facility does increase the number of stations in Buncombe County, it is based on the facility need methodology. It ultimately serves to meet the needs of the facility’s growing population of patients referred by the facility’s admitting nephrologists. The addition of stations, therefore, serves to increase capacity rather than duplicate any existing or approved services in the service area.”

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

- The applicant proposes to increase the number of dialysis stations at Weaverville Dialysis based on Condition 2 of the facility need determination in the 2025 SMFP.
- The applicant adequately demonstrates that the 10 proposed dialysis stations are needed in addition to the existing or approved dialysis stations in Buncombe County based on the facility’s historical patient population growth.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

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

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

The applicant proposes to add no more than 10 IC dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 30 IC 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 02/28/2025	CY2027	CY2028
Administrator	1.00	1.00	1.00
Registered Nurses (RNs)	2.50	3.75	3.75
Technicians (PCT)	7.50	11.00	11.00
Dietician	0.50	0.50	0.50
Social Worker	0.50	0.50	0.50
Administration/Business Office	1.00	1.00	1.00
Other- Biomedical Tech	0.50	0.50	0.50
Total	13.50	18.25	18.25

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.4. In Section H, pages 49-50, 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 projects the type, and the number of positions based on federal guidelines and what is required to maintain quality of care based on facility's station count and patient census.
- The applicant has existing policies regarding recruitment, qualifications for staff, training, and continuing education.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

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The applicant proposes to add no more than 10 IC dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 30 IC dialysis stations upon project completion.

Ancillary and Support Services

In Section I, page 52, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 52-54, the applicant explains how each ancillary and support service is made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available.

Coordination

In Section I, page 54, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the facility's established relationships with other physicians and hospitals in the area and the continued relationships with them based on letters provided by the Administrator and Medical Director.

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.

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 64, the applicant provides the historical payor mix during CY 2024 for the proposed services, as shown in the table below.

Payor Source	Weaverville Dialysis Historical Payor Mix CY 2024	
	In-Center	
	# of Patients	% of Total
Self-Pay	0	0.0%
Insurance*	1	1.4%
Medicare*	55	78.6%
Medicaid*	6	8.6%
Other (VA)	8	11.4%
Total	70	100.0%

*Including any managed care plans.

In Section L, page 65, the applicant provides the following comparison.

	Percentage of Total Patients Served	Percentage of the Population of the Service Area *
Female	45.6%	51.8%
Male	54.4%	48.2%
Unknown	0.0%	0.0%
64 and Younger	38.2%	78.2%
65 and Older	61.8%	21.8%
American Indian	0.0%	0.6%
Asian	0.0%	1.5%
Black or African American	13.2%	6.0%
Native Hawaiian or Pacific Islander	0.0%	0.2%
White or Caucasian	85.3%	89.4%
Other Race	1.5%	2.3%
Declined / Unavailable	-	-

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

The Agency reviewed the:

- Application
- Exhibits to the application

- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and persons with disabilities to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

In Section L, page 65, the applicant states that the facility is not obligated to provide uncompensated care, community service or access by minorities and persons with disabilities.

In Section L, page 65, 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 66, 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.

Payor Source	Weaverville Dialysis Projected Payor Mix CY 2028	
	In-Center	
	# of Patients	% of Total
Self-Pay	0.00	0.0%
Insurance*	1.29	1.4%
Medicare*	70.86	78.6%
Medicaid*	7.73	8.6%
Other (VA)	10.31	11.4%
Total	90.19	100.0%

*Including any managed care plans.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 78.6% of total services will be provided to Medicare patients and 8.6% to Medicaid patients.

On page 66, 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 based on the following:

- The applicant projects payor mix based on the facility's patient payment during the last full fiscal year.
- The applicant calculates payor mix based on the facility's historical patient census and actual data related to percentages by payor source.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons 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 67, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application

- Exhibits to the application

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

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

The applicant proposes to add no more than 10 IC dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 30 IC dialysis stations upon project completion.

In Section M, page 69, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.1. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following:

- The applicant states that it has offered Weaverville Dialysis as a clinical learning site for nursing students from Asheville-Buncombe Technical Community College.
- In supporting documentation, the applicant provides the letter sent to Asheville-Buncombe Technical Community College offering the facility as a clinical learning site.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall

demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to add no more than 10 IC dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 30 IC dialysis stations upon project completion.

On page 113, the 2025 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.” Weaverville Dialysis is in Buncombe County. Thus, the service area for this facility consists of Buncombe County. Facilities may serve residents of counties not included in their service area.

According to the 2025 SMFP, Table 9A, page 119, there are four existing or approved dialysis facilities in Buncombe County, as shown in the following table:

Buncombe County					
	Certified Stations as of 12/31/2023*	Number of In-center Patients as of 12/31/2023*	Utilization by Percent as of 12/31/2023*	Patients per Station as of 12/31/2023*	Number of Additional Stations Approved*
Arden Dialysis	14	47	83.93%	3.36	0
Asheville Kidney Center	52	104	50.00%	2.00	-4
Biltmore Home Training	0	0	0.00%	0.00	4
Weaverville Dialysis	20	69	86.25%	3.45	0
Total	86	220	63.95%		

*Source: Table on page 46 of the application and from the 2025 SMFP, Table 9A, page 119.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 71, the applicant states:

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

The expansion of Weaverville Dialysis 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 71, the applicant states:

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

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

Regarding the impact of the proposal on quality, in Section N, page 71, the applicant states:

“The expansion of Weaverville Dialysis will enhance accessibility to dialysis for current and projected patients and, by reducing the economic and physical burdens on our patients, this project this project will enhance the quality...of our services...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 71, 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 of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

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

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

C

In Section Q, Form O, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 105 of this type of facility located in North Carolina.

In Section O, page 75, the applicant states that, during the 18 months immediately preceding the submittal of the application, DaVita-operated facilities in North Carolina have provided quality care and are in compliance with CMS' Conditions for Coverage. On page 74, the applicant states: "*DaVita is committed to providing quality care to the ESRD population through a comprehensive Quality Management Program.*" After reviewing and considering information provided by the applicant and considering the quality of care provided at all 105 facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

G.S. 131E-183 (b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The application is conforming to all applicable criteria, as discussed below.

10 NCAC 14C .2203 PERFORMANCE STANDARDS

- (a) *An applicant proposing to establish a new kidney disease treatment center or dialysis facility shall document the need for at least 10 dialysis stations based on utilization of 2.8 in-center patients per station per week as of the end of the first full fiscal year of operation following certification of the facility. An applicant may document the need for less than 10 stations if the application is submitted in response to an adjusted need determination in the State Medical Facilities Plan for less than 10 stations.*
- NA- Weaverville Dialysis is an existing facility. Therefore, this Rule is not applicable to this review.
- (b) *An applicant proposing to increase the number of in-center dialysis stations in:*
- (1) *an existing dialysis facility; or*
 - (2) *a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need; shall document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per station per week as of the end of the first full fiscal year of operation following certification of the additional stations.*
- C- In Section C, page 25, and on Form C in Section Q, the applicant projects to serve 85 IC patients on 30 stations, or a rate of 2.83 in-center patients per station per week (85 patients / 30 stations = 2.83), 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 to this review.
- (d) *An applicant proposing to increase the number of home hemodialysis stations in a dialysis facility dedicated to home hemodialysis or peritoneal dialysis training shall document the need for the total number of home hemodialysis stations in the facility based on training six home hemodialysis patients per station per year as of the end of the first full fiscal year of operation following certification of the additional stations.*
- NA- As of the date of this review, Weaverville Dialysis does not serve home hemodialysis patients. Therefore, this Rule does not apply.
- (e) *An applicant shall provide the assumptions and methodology used for the projected utilization required by this Rule.*

- C- In Section C, pages 24-25, and in Section Q, Form C Utilization and Assumptions and Methodology, pages 82-83, 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.