REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conforming as Conditioned
NC = Nonconforming
NA = Not Applicable

Decision Date: June 26, 2026
Findings Date: June 26, 2026

Project Analyst: Yolanda W. Jackson
Co-Signer: Gloria C. Hale

Project ID #: G-12762-26
Facility: Burlington Dialysis
FID #: 956036
County: Alamance
Applicant: Renal Treatment Centers – Mid-Atlantic, Inc.
Project: Add no more than two in-center dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 22 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

Renal Treatment Centers – Mid-Atlantic, Inc. (hereinafter referred to as "the applicant") proposes to add no more than two in-center dialysis stations at Burlington Dialysis pursuant to Condition 2 of the facility need methodology for a total of no more than 22 stations upon project completion.

Need Determination (Condition 2)

Chapter 9 of 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 Alamance 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 113 of the 2026 SMFP, is 87.50% or 3.5 patients per station per week, based on 70 in-center dialysis patients and 20 certified dialysis stations (70 patients / 20 stations / 4 =87.50%).

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

The applicant proposes to add no more than two new stations to the facility, which is consistent with the 2026 SMFP calculated facility need determination for up to seven 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.*"

In Section, B, page 20, the applicant provides the following table that reflects the patient demographics at Burlington Dialysis.

Group	Last Full FY before Submission of the Application	
	Percentage of Total Patients Served	Percentage of the Population of the Service Area
Low-income persons	87.3%	13.8%
Racial and ethnic minorities	58.7%	29.6%
Women	47.6%	52.0%
Persons with disabilities	100.0%	7.9%
Persons 65 and older	41.3%	17.6%
Medicare beneficiaries	73.0%	N/A
Medicaid recipients	14.3%	N/A
Language: English	85.7%	85.0%
Language: Other	14.3%	15.0%
High school graduate or higher	N/A	89.0%
Percent of population – Urban*	N/A	73.6%
Percent of population – Rural*	N/A	26.4%

*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.

In Section B, pages 20–21, 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
- 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 2026 SMFP.
- The applicant adequately demonstrates that the application is consistent with Policy *GEN-5* based on:
    - The applicant provided patient demographics for Alamance County patients and the general population.
    - The applicant described the strategies it will implement to provide culturally competent services to members of the medically underserved community including interpretation and translation services to patients who have limited English proficiency, providing health equity and cultural humility training to all teammates, and regularly reviewing health equity data so that potential health equity disparities can be identified and plans can be developed to address health equity disparities.
    - The applicant described how it will measure and periodically assess increased equitable access to healthcare services and reduction in health disparities including collecting specific demographic and social drivers of health data, assessing data and performance for different patient populations, engaging in quality improvement activity, 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 two in-center dialysis stations at Burlington Dialysis pursuant to Condition 2 of the facility need methodology for a total of no more than 22 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."* Burlington Dialysis is located in Alamance County. Thus, the service area for this facility consists of Alamance County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates historical and projected patient origin.

County	Historical CY2025		Second Full FY of Operation following Project Completion CY2029	
	# of In-center Patients	% of Total	# of In-center Patients	% of Total
Alamance	50	79.4%	54	80.6%
Caswell	1	1.6%	1	1.5%
Davidson	1	1.6%	1	1.5%
Durham	1	1.6%	1	1.5%
Guilford	9	14.3%	9	13.4%
Wake	1	1.6%	1	1.5%
Total	**63**	**100.0%**	**67**	**100.0%**

Source: Section C, pages 23–24.

In Section C, pages 24-25, 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 of the future patient population to be served with the facility census as of December 31, 2025.

- The applicant projected growth of the Alamance County patient population using the Alamance County 5-Year Average Change Rate (5-Year AACR) of 2.0%, as published in the 2026 SMFP.

- Burlington Dialysis has 13 in-center patients residing outside of Alamance County. The applicant does not project any growth of this segment of the patient population but will carry these patients forward at appropriate points in time.

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:

> "*The addition of stations serves to increase capacity and proactively address the issues of growth and access at this 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.

Projected Utilization

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

Form C Utilization	Last Full FY CY2025	Interim Full FY CY2026	Interim Full FY CY2027	1st Full FY CY2028	2nd Full FY CY2029
In-Center Patients					
# of Patients at Beginning of Year	70.00	63.00	64.00	65.02	66.06
# of Patients at the End of the Year	63.00	64.00	65.02	66.06	67.12
Avg. # of Patients During the Year	66.50	63.50	64.51	65.54	66.59
# of Treatments / Patient / Year	139.91	148.20	148.20	148.20	148.20
Total # of Treatments	9,304.00	9,410.70	9,560.38	9,713.06	9,868.79

In Section Q, page 82, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

In-Center Methodology

	IC Stations	IC Patients
The applicant begins with the station count and patient census as of 12/31/2025.	20	63
The applicant projects the Alamance County patient census forward one year to 12/31/2026 using the county's five-year AACR of 2.0%.		50 x 1.020 = 51.00
The applicant adds the patients from outside Alamance County. This is the projected ending census for Interim Year 1.		51.00 + 13 = 64.00
The applicant projects the Alamance County patient census forward one year to 12/31/2027 by applying the five-year AACR.		51.00 X 1.020 = 52.02
The applicant adds the patients from outside Alamance County. This is the projected ending census for Interim Year 2.		52.02 + 13 = 65.02
The proposed project is projected to be certified on 1/1/2028. This is the station count at the beginning of the projects first full fiscal year (FY1). The applicant projects the Alamance County patient population forward one year to 12/31/2028 by applying the five-year AACR.	20 + 2=22	52.02 x 1.020 = 53.06
The applicant adds the patients from outside Alamance County. This is the projected ending census for FY1.		53.06 + 13 = 66.06
The applicant projects the Alamance County patient census forward one year to 12/31/2029 by applying the five-year AACR.		53.06 X 1.020 = 54.12
The applicant adds the patients from outside Alamance County. This is the projected ending census for FY2.		54.12 + 13 = 67.12

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

- The applicant projects future utilization for in-center patients by increasing the current Alamance County patient population by the Alamance County 5-Year AACR in the 2026 SMFP of 2.0%.
- The applicant assumes that patients residing outside of Alamance County will continue dialysis at Burlington Dialysis as a function of patient choice. However, the applicant does not project any growth of this segment of the patient population.
- Projected utilization at the end of first full fiscal year of operation meets the minimum of 2.8 patients per station per week (66.06 patients / 22 stations = 3.0) as 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.*
>
> *…*
>
> *Burlington 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.*"

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

Group	Estimated Percentage of Total Patients during the Second Full Fiscal Year
Low income persons	87.3%
Racial and ethnic minorities	58.7%
Women	47.6%
Persons with Disabilities	100.0%
Persons 65 and older	41.3%
Medicare beneficiaries	73.0%
Medicaid recipients	14.3%

Source: Section C, page 28.

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 two in-center dialysis stations at Burlington Dialysis pursuant to Condition 2 of the facility need methodology for a total of no more than 22 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 less effective given the growth rate at the facility.
- **Relocate stations from another DaVita facility**. The applicant states that three of the DaVita facilities in Alamance County are operating at less than 75% capacity. The applicant states that relocating stations from Glen Raven Dialysis and Mebane Dialysis will negatively impact the patients presently being served by the facilities given that they operate three days a week to meet the needs of their patients and the scheduling requirements of the physicians. The applicant states that relocating stations from North Burlington Dialysis would eliminate currently available first shift appointment times and increase utilization to greater than 3.5 patients per station. Therefore, this is a less effective alternative.

In Section C, page 26, the applicant states that its proposal is the most effective alternative because the addition of stations serves to increase capacity and proactively address the issues of growth and access at the facility.

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

- The applicant's proposal is in response to a facility need pursuant to Condition 2 of the facility need methodology, as reported in the 2026 SMFP.
- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

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. **Renal Treatment Centers – Mid-Atlantic, Inc. (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 two additional in-center dialysis stations at Burlington Dialysis for a total of no more than 22 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 December 1, 2026.**

5. **The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**

(5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to add no more than two in-center dialysis stations at Burlington Dialysis pursuant to Condition 2 of the facility need methodology for a total of no more than 22 stations upon project completion.

Capital and Working Capital Cost

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

Medical Equipment	$27,000
Non-Medical Equipment	$7,500
Furniture	$4,000
Total	**$38,500**

In Section Q, page 86, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant states that the Project Manager for North Carolina partnered with Finance to develop the capital costs for this project.
- The applicant states that they used a corporate model and regional database along with inputs from operations and the regional Real Estate team to ensure project costs are reasonable.

In Section F.3, pages 40–41, the applicant states there will be no start-up costs or initial operating expenses because Burlington Dialysis is an existing facility.

Availability of Funds

In Section E, page 39, the applicant states that the capital cost will be funded with its cash reserves. In Exhibit F.2.c, the applicant provides a letter dated March 6, 2026, from the Chief Accounting Officer of DaVita Kidney Care, stating that DaVita is willing to commit cash reserves for the capital cost of the proposed project. DaVita is the parent company and 100% owner of Renal Treatment Centers – Mid-Atlantic, Inc. The applicant also provides Consolidated Balance Sheets for Davita, Inc. for the fiscal year ending December 31, 2025, in Exhibit F.2. which shows it has adequate funds for 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. On Form F.2, in Section Q, the applicant projects that revenues will exceed operating expenses in the two full fiscal years following completion of the project, as shown in the table below.

	1st Full Fiscal Year CY2028	2nd Full Fiscal Year CY2029
Total # of Treatments	9,713	9,869
Total Gross Revenues (Charges)	$3,155,202	3,205,789
Total Net Revenue	$3,141,341	$3,191,706
Average Net Revenue per Treatment	$323	$323
Total Operating Expenses (Costs)	$2,088,201	$2,131,632
Average Operating Expense per Treatment (All Sources)	$215	$216
Net Income	$1,053,140	$1,060,074

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q, pages 90 and 92. 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 and operating expenses including projected reimbursement rates by payor source 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 because 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.

(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 two in-center dialysis stations at Burlington Dialysis pursuant to Condition 2 of the facility need methodology for a total of no more than 22 stations upon project completion.

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." Burlington Dialysis is in Alamance County. Thus, the service area for this facility consists of Alamance County. Facilities may also serve residents of counties not included in their service area.

According to the 2026 SMFP, Table 9A, page 113, there are seven existing or approved dialysis facilities in Alamance County, as shown in the following table:

Facility	Certified Stations 12/31/2024	Number In-Center Patients 12/31/2024	Utilization Rate 12/31/2024
Alamance County Dialysis	16	53	82.81%
BMA of Burlington	33	77	58.33%
Burlington Dialysis	20	70	87.50%
FMC Mebane	27	79	73.15%
Glen Raven Dialysis	14	28	50.00%
Mebane Dialysis	18	36	50.00%
North Burlington Dialysis	18	46	63.89%

Source: Table 9A, 2026 SMFP, page 113.

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 Alamance County. The applicant states:

> "*Based on the facility need methodology in the 2025 [2026] SMFP under Condition 2, Burlington Dialysis qualifies to add up to 7 dialysis stations.*
>
> *… While adding stations at this facility does increase the number of stations in Alamance 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 will 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 seven dialysis stations at Burlington Dialysis.
- The applicant adequately demonstrates that the two proposed dialysis stations are needed in addition to the existing or approved dialysis stations in Alamance County.

Conclusion

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 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 two in-center dialysis stations at Burlington Dialysis pursuant to Condition 2 of the facility need methodology for a total of no more than 22 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 02/28/2026	**2nd Full Fiscal Year** ***CY2029***
Administrator	1.00	1.00
Registered Nurses (RNs)	2.50	2.75
Technicians (PCT)	7.50	8.25
Dietician	0.50	0.50
Social Worker	0.50	0.50
Administration/Business Office	1.00	1.00
Biomedical Tech	0.50	0.50
Total	**13.50**	**14.50**

The assumptions and methodology used to project staffing are provided in Section Q, page 94. 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 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 because Burlington Dialysis is an existing facility and it offers a wide range of personnel benefits to attract qualified staff.

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 two in-center dialysis stations at Burlington Dialysis pursuant to Condition 2 of the facility need methodology for a total of no more than 22 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 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 54, the applicant describes its existing relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on its established relationships with other healthcare providers and social service agencies in Alamance 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 64, the applicant provides the historical payor mix during CY2025 for the proposed services, as shown in the table below.

Payor Source	Burlington Dialysis	
	In-Center Dialysis	
	# of Patients	% of Total
Self-Pay	0	0.0%
Insurance*	5	7.9%
Medicare*	46	73.0%
Medicaid*	9	14.3%
Other-VA	3	4.8%
Total	**63**	**100.0%**

*Including any managed care plans.

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

Burlington Dialysis	Last Full FY before Submission of the Application	
	Percentage of Total Patients Served	Percentage of the Population of the Service Area*
Female	47.6%	52.0%
Male	52.4%	48.0%
Unknown	0.0%	0.0%
64 and Younger	58.7%	82.4%
65 and Older	41.3%	17.6%
American Indian	0.0%	1.6%
Asian	0.0%	2.4%
Black or African-American	55.6%	22.7%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	41.3%	70.3%
Other Race	3.2%	2.8%
Declined / Unavailable	0.0%	0.0%

*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. Just enter in the name of the county.

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

In Section L, page 65, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights equal access complaints have been filed against Burlington Dialysis.

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	Burlington Dialysis Projected Payor Mix during the 2nd Full FY CY2029	
	In-Center Dialysis	
	# of Patients	% of Total
Self-Pay	0.00	0.0%
Insurance *	5.33	7.9%
Medicare*	49.01	73.0%
Medicaid*	9.59	14.3%
Other-VA	3.20	4.8%
Total	**67.12**	**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 73.0% of total services will be provided to Medicare patients and 14.3% 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 projected payor mix is based on the sources of payment that have been received in the last full fiscal year at Burlington Dialysis.
- The patient counts in each payor category are based on the historical patient census.

The Agency reviewed the:

- Application
- Exhibits to the application

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

(d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section L, page 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 two in-center dialysis stations at Burlington Dialysis pursuant to Condition 2 of the facility need methodology for a total of no more than 22 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 has offered Burlington Dialysis as a clinical learning site for nursing students from UNC Greensboro.
- In Exhibit M.1, the applicant provides a copy of the student training agreement with UNC Greensboro.

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 two in-center dialysis stations at Burlington Dialysis pursuant to Condition 2 of the facility need methodology for a total of no more than 22 stations upon project completion.

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."* Burlington Dialysis is in Alamance County. Thus, the service area for this facility consists of Alamance County. Facilities may also serve residents of counties not included in their service area.

According to the 2026 SMFP, Table 9A, page 113, there are seven existing or approved dialysis facilities in Alamance County, as shown in the following table:

Facility	Certified Stations 12/31/2024	Number In-Center Patients 12/31/2024	Utilization Rate 12/31/2024
Alamance County Dialysis	16	53	82.81%
BMA of Burlington	33	77	58.33%
Burlington Dialysis	20	70	87.50%
FMC Mebane	27	79	73.15%
Glen Raven Dialysis	14	28	50.00%
Mebane Dialysis	18	36	50.00%
North Burlington Dialysis	18	46	63.89%

Source: Table 9A, 2026 SMFP, page 113.

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

> "*The expansion of Burlington Dialysis will have no effect on competition in Alamance County. Although the addition of stations at this facility could serve to provide more patients another option to select a provider that gives them the highest quality service and better meets their needs, this project primarily serves to address the needs of a population already served (or projected to be served, based on historical growth rates) by DaVita.*"

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

> "*The expansion of Burlington 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:

"*...Davita is committed to providing quality care to the ESRD population*"

See also Sections B and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 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, B, and C of the application and any exhibits.

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

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

The applicant proposes to add no more than two in-center dialysis stations at Burlington Dialysis pursuant to Condition 2 of the facility need methodology for a total of no more than 22 stations upon project completion.

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 104 dialysis facilities owned, operated, or managed by the applicant or a related entity located in North Carolina.

In Section O, page 76, 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 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 12 months 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- Burlington Dialysis is an existing facility. Therefore, this Rule is not applicable to this review.

(b) An applicant proposing to increase the number of dialysis stations in:

(1) an existing dialysis facility; or
(2) a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need; shall document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the additional stations.

-C- In Section C, page 29, and in Section Q, page 82, the applicant projects to serve 66 in-center patients on 22 stations, or a rate of 3.0 in-center patients per station per week (66 patients / 22 stations = 3.0), 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) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*

-C- In Section C, pages 24–25, and in Section Q, page 82, 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.