

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: June 25, 2025

Findings Date: July 2, 2025

Project Analyst: Ena Lightbourne

Co-Signer: Micheala Mitchell

Project ID #: B-12618-25

Facility: Arden Dialysis

FID #: 150248

County: Buncombe

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

Project: Add no more than 2 in-center dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 16 in-center 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 2 in-center (IC) dialysis stations at Arden Dialysis pursuant to Condition 2 of the facility need methodology for a total of no more than 16 IC stations upon project completion. According to the 2025 ESRD data collection forms, Arden 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. The utilization rate reported for Arden Dialysis is 83.93% or 3.357 patients per station per week, based on 47 in-center dialysis patients and 14 certified dialysis stations ( $47 \text{ patients} / 14 \text{ stations} = 3.357$ ;  $3.357 / 4 = 0.8393$  or 83.93%).

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 Arden Dialysis is up to 7 additional stations: thus, the applicant is eligible to apply to add up to 7 stations during the 2025 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than 2 new stations to the facility, which is less than the 2025 SMFP calculated facility need determination for up to 7 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 Arden 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 two IC dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 16 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.*” Arden 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.

Arden Dialysis Historical and Projected Patient Origin					
Historical			Projected		
01/01/2024-12/31/2024 CY 2024			01/01/2028-12/31/2028 CY 2028 (2 <sup>nd</sup> Project Year)		
County	# of In-Center Patients	% of Total	County	# of In-Center Patients	% of Total
Buncombe	30	38.0%	Buncombe	30	38.0%
Henderson	46	58.2%	Henderson	46	58.2%
Polk	2	2.5%	Polk	2	2.5%
South Carolina	1	1.3%	South Carolina	1	1.3%
<b>Total</b>	<b>79</b>	<b>100.0%</b>	<b>Total</b>	<b>79</b>	<b>100.0%</b>

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 does not project growth in patient census based on the continuing impact of Hurricane Helene.

### **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 7 stations for Arden Dialysis, which had 14 existing stations, as reported in Tables 9D and 9A of the 2025 SMFP...we demonstrate that an additional 2 stations will be well utilized by the population to be served, the current and projected in-center patients of Arden 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 historical growth in the patient population and the need to maintain 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.

<b>Arden Dialysis Projected Utilization</b>		
	<b>IC stations</b>	<b>IC patients</b>
Station count and patient census at the facility as of December 31, 2024.	14	79
The facility's patient census is projected forward a year to December 31, 2025 and is increased by 0%. The is the ending census as of the end of interim Year 1.		$79 \times 1.0 = 79$
The facility's patient census is projected forward a year to December 31, 2026. The is the ending census as of the end of interim Year 2.		$79 \times 1.0 = 79$
The proposed project is projected to be certified on January 1, 2027. This is the station count at the beginning of FY1.	$14 + 2 = 16$	
The facility's patient census is projected forward a year to December 31, 2027. This is the ending census for FY1.		$79 \times 1.0 = 79$
The facility's patient census is projected forward a year to December 31, 2028, and is increased by 0%. The is the ending census as of the end of FY2.		$79 \times 1.0 = 79$

In Section C, pages 24-25 and Section Q, page 82, 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 79 IC patients on 14 dialysis stations. Of the 79 patients, 49 resided outside of Buncombe County. The applicant does not project growth for this population.
- The applicant grew the patient census using a conservative grow rate of 0%, based on the continuing impact of Hurricane Helene.

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

- FY1: 4.9 patients per station per week or 123.4% ( $79 \text{ patients} / 16 \text{ stations} = 4.938/4 = 0.1234$  or 123.4%)
- FY2: 4.9 patients per station per week or 123.4% ( $79 \text{ patients} / 16 \text{ stations} = 4.938/4 = 0.1234$  or 123.4%), an increase of 0%.

The projected utilization of 4.9 patients per station per week at the end of FY1 exceeds the minimum standard of 2.8 in-center patients per station per week required by 10A NCAC 14C .2203(b).

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 no growth in the IC patient census through the second year of the project based on the continued impact of Hurricane Helene.
- The applicant's proposal to add two dialysis stations will meet the need to maintain access to dialysis services for the facility's patient population.
- Projected utilization at the end of OY1 exceeds the minimum of 2.8 patients per station per week required by 10A NCAC 14C .2203(b).

### **Access to Medically Underserved Groups**

In Section C, page 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.*

*Arden 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.

<b>Medically Underserved Groups</b>	<b>Estimated Percentage of Total Patients during the Second Full Fiscal Year</b>
Low-income persons	92.4%
Racial and ethnic minorities	23.0%
Women	43.2%
Persons with Disabilities	100.0%
Persons 65 and older	51.4%
Medicare beneficiaries	82.3%
Medicaid recipients	10.1%

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 two IC dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 16 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 historical growth rate. According to the 2025 ESRD data collection forms, the facility had 141.00% utilization rate as of December 31, 2024 (79 patients / 14 stations = 5.64 / 4 = 1.41 or 141.00%).
- 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. Weaverville 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 operates under 75% capacity, DaVita determined that the facility should maintain capacity for



displaced patients due to the impact of Hurricane Helene. Also, in Project ID# B-12428-23, the applicant was approved to relocate four stations from Asheville Kidney Center to add to Biltmore Home Training.

- Add More than the Proposed Number of Stations-The applicant states that this would not be a cost-effective alternative because the facility plant cannot accommodate more than the two proposed stations. Expansion of the facility would require additional cost. Furthermore, some patients currently dialyzing at Arden Dialysis will return to Hendersonville Dialysis once the damage from Hurricane Helene is repaired.

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 Arden 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 2 in-center dialysis stations at Arden Dialysis for a total of no more than 16 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 two IC dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 16 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	
Medical Equipment	\$27,000
Non-Medical Equipment	\$8,440
Furniture	\$4,000
<b>Total</b>	<b>\$39,440</b>

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.

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 accumulative reserves. The Project Analyst concludes that the applicant is referring to Davita's accumulative 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-4 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 and working 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.

Arden Dialysis	1 <sup>st</sup> Project Year	2 <sup>nd</sup> Project Year
	CY2027	CY2028
Total Treatments	11,708	11,708
Total Gross Revenues (Charges)	\$3,650,759	\$3,650,759
Total Net Revenue	\$3,487,088	\$3,487,088
Average Net Revenue per Treatment	\$298	\$298
Total Operating Expenses (Costs)	\$2,598,220	\$2,627,239
Average Operating Expense per Treatment	\$222	\$224
Net Income	\$888,868	\$859,849

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 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 two IC dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 16 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.” Arden 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
<b>Total</b>	<b>86</b>	<b>220</b>	<b>63.95%</b>		

\*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, Arden Dialysis qualifies to add up to 7 dialysis stations.*

*...we demonstrate the need that Arden 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 Arden Dialysis based on Condition 2 of the facility need determination in the 2025 SMFP.
- The applicant adequately demonstrates that the two 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 two IC dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 16 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)	1.75	2.00	2.00
Technicians (PCT)	5.25	6.00	6.00
Dietician	1.00	1.00	1.00
Social Worker	1.00	1.00	1.00
Administration/Business Office	1.00	1.00	1.00
Other- Biomedical Tech	0.50	0.50	0.50
<b>Total</b>	<b>11.50</b>	<b>12.50</b>	<b>12.50</b>

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 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.

The applicant proposes to add no more than two IC dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 16 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 healthcare providers in the area and the continued agreements with the facility's 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.

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 renovating 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	Arden Dialysis Historical Payor Mix CY 2024	
	In-Center	
	# of Patients	% of Total
Self-Pay	0	0.0%
Insurance*	5	6.3%
Medicare*	65	82.3%
Medicaid*	8	10.1%
Other (VA)	1	1.3%
<b>Total</b>	<b>79</b>	<b>100.0%</b>

\*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	43.2%	51.8%
Male	56.8%	48.2%
Unknown	0.0%	0.0%
64 and Younger	48.6%	78.2%
65 and Older	51.4%	21.8%
American Indian	0.0%	0.6%
Asian	1.4%	1.5%
Black or African American	17.6%	6.0%
Native Hawaiian or Pacific Islander	1.4%	0.2%
White or Caucasian	77.0%	89.4%
Other Race	2.7%	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	Arden Dialysis Projected Payor Mix CY 2028	
	In-Center	
	# of Patients	% of Total
Self-Pay	0	0.0%
Insurance*	5	6.3%
Medicare*	65	82.3%
Medicaid*	8	10.1%
Other (VA)	1	1.3%
<b>Total</b>	<b>79</b>	<b>100.0%</b>

\*Including any managed care plans.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 82.3% of total services will be provided to Medicare patients and 10.1% 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 applicant accounts for the possible change in payor source during the year.

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 two IC dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 16 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 applicant's statement that it has offered Arden Dialysis as a clinical learning site for nursing students from Asheville-Buncombe Technical Community College.

### **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 IC dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 16 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.*” Arden 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
<b>Total</b>	<b>86</b>	<b>220</b>	<b>63.95%</b>		

\*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 bottom line is the expansion of Arden Dialysis will enhance accessibility and/or convenience 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 Arden Dialysis will enhance accessibility to dialysis for current and projected patients and, by reducing the economic and physical burdens on our patients, this project will enhance the quality and cost effectiveness of our services because it will make it easier for patients, family members and others involved in the dialysis process to receive services.”*

See also Sections 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 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- Arden 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 Section Q, page 82, the applicant projects to serve 79 IC patients on 16 stations, or a rate of 4.93 in-center patients per station per week ( $79 \text{ patients} / 16 \text{ stations} = 4.93$ ), 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, Arden 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, 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.