

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: October 27, 2023

Findings Date: October 27, 2023

Project Analyst: Crystal Kearney

Co-Signer: Lisa Pittman

Project ID #: N-012407-23

Facility: Dialysis Care of Hoke County

FID #: 945165

County: Hoke

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

Project: Add no more than 3 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 28 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., (“the applicant”), proposes to add no more than 3 in-center (IC) dialysis stations to Dialysis Care of Hoke County (“DC Hoke”) pursuant to Condition 2 of the facility need methodology for a total of no more than 28 IC dialysis stations upon project completion.

#### **Need Determination (Condition 2)**

Chapter 9 of the 2023 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, page 132, the county need methodology shows there is not a county need determination for additional dialysis stations in Hoke 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 2023 SMFP, if the utilization rate for the facility as reported in the 2023 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 the facility is 79.00 percent or 3.16 patients per station per week, based on 79 in-center dialysis patients and 25 certified dialysis stations  $79 \text{ patients} / 25 \text{ stations} = 3.16$ :  $3.16 / 4 = 79\%$ ).

As shown in Table 9A, based on the facility need methodology for dialysis stations, the potential number of stations needed is up to six additional stations; thus, the applicant is eligible to apply to add up to six stations during the 2023 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than three new stations to the facility, which is consistent with the 2023 SMFP calculated facility need determination for up to six stations; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

### **Policies**

There is one policy in the 2023 SMFP that is applicable to this review, Policy GEN-3: *Basic Principles*.

Policy *GEN-3*, page 30 of the 2023 SMFP, states:

*“A certificate of need applicant applying to develop or offer 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 promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”*

### **Promote Safety and Quality**

The applicant describes how it believes the proposed project will promote safety and quality in Section B, page 21; Section N, pages 76-77; Section O, pages 79-81; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote safety and quality.

### **Promote Equitable Access**

The applicant describes how it believes the proposed project will promote equitable access in Section B, pages 21- 22; Section C, page 31; Section L, pages 68-72; Section N, page 76; and

referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant's proposal will promote equitable access.

### Maximize Healthcare Value

The applicant describes how it believes the proposed project will maximize healthcare value in Section B, page 22; Section F, pages 43-48; Section N, page 76; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant's proposal will maximize healthcare value.

The applicant adequately demonstrates how its proposal incorporates the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need as identified by the applicant. Therefore, the application is consistent with policy GEN-3.

### 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 Condition 2 of the facility need methodology as applied from the 2023 SMFP.
  - The applicant adequately demonstrates how Dialysis Care of Hoke County's projected volumes incorporate the concepts of safety and quality, equitable access and maximum value for resources expended in meeting the facility need and is consistent with Policy GEN-3. (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

Dialysis Care of Hoke County proposes to add no more than 3 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 28 stations upon project completion.

### Patient Origin

On page 113, the 2023 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located.* Thus, the service area for this facility consists of Hoke County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates historical and projected patient origin.

County	Dialysis Care of Hoke County Patient Origin			
	Historical Last Full FY CY 2022		Projected 2 <sup>nd</sup> Full FY CY 2026	
	# of IC Patients	% of Total	# of IC Patients	% of Total
Hoke	66	85.7%	80.8075	77.8%
Bladen	1	1.3%	2	1.9%
Cumberland	4	5.2%	13	12.5%
Moore	2	2.6%	3	2.9%
Robeson	4	5.2%	2	1.9%
Other States			3	2.9%
<b>Total</b>	<b>77</b>	<b>100.0%</b>	<b>103.8075</b>	<b>100.0%</b>

Source: Section C, pages 25 - 26

In Section C, pages 25-29 and Section Q, pages 86-88, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s patient origin projections are reasonable and adequately supported because they are based the historical (CY2022 and January – May 2023) patient origin for the facility and projected forward using the Hoke County Five-Year Average Annual Change Rate (AACR) of 5.8%, as published in the 2023 SMFP.

**Analysis of Need**

In Section C, page 28, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 30, the applicant states:

*“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 2023 SMFP. The discussion regarding the 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.

Projected Utilization

In Section C, pages 25-30, and Section Q, page 88, the applicant provides projected utilization, as illustrated in the following table.

DC Hoke	IC Stations	IC Patients
The application begins with 89 patients dialyzing on 25 stations at the facility as of 5/31/2023.	25	89
The facility’s Hoke County patient census is projected from 6/1/2023 forward to 12/31/2023 and is increased by 7/12 of the Five-Year AACR for Hoke County.		$66 \times 1.0338 = 68.2330$
The 33 patients from outside Hoke County are added to the facility’s census. This is the ending census as of 12/31/2023.		$68.23 + 23 = 91.23$
The facility’s Hoke County patient census is projected forward a year to 12/31/2024 and is increased by the Five -Year AACR for Hoke County, 5.8%.		$68.23 \times 1.058 = 72.1905$
The 23 patients from outside Hoke County are added to the facility’s census. This is the ending census for the first full interim year.		$72.19 + 23 = 95.19$
The proposed project is projected to be certified on 01/91/2025. This is the station count at the beginning of the project’s first full fiscal year (FY1) The facility’s Hoke County patient census is projected forward a year to 12/31/2025 and is increased by 5.8%	$25 + 3 = 28$	$72.19 \times 1.058 = 76.3776$
The 23 patients from outside Hoke County are added to the facility’s census. This is the ending census for FY1.		$76.38 + 23 + 99.38$
The facility’s Hoke County patient census is projected forward a year to 12/31/2026 and is increased by 5.8%.		$76.38 \times 1.058 = 80.8075$
The 23 patients from outside Hoke County are added to the facility’s census. This is the ending census as of the project’s second full fiscal year (FY2).		$80.81 + 23 = 103.81$

In Section C, pages 26-30, and Section Q, pages 88, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The applicant begins its projections with patient population at DC Hoke as of May 31, 2023, which included 89 IC patients. Of these 89 patients, 66 lived in the service area, Hoke County, and 23 lived outside of the service area.
- The period of growth begins June 1, 2023, and is calculated forward to December 31, 2026. No growth calculations were performed for the patients living outside of Hoke County.  
 Operating Year 1 is the period from January 1-December 31, 2025  
 Operating Year 2 is the period from January 1- December 31, 2026
- Although the growth rate during the first five months of 2023 was over 15%, the following patient projections utilize the 5-Year AACR of 5.8% for the IC patients living in Hoke County.

Based upon these calculations, DC Hoke projects to serve the following number of patients for the Operating Years 1 & 2.

	Operating Year 1	Operating Year 2
In-center	99	103

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

By the end of FY1 DC Hoke is projected to have

- 99 patients / 28 certified stations= 3.54 patients/station
- $3.54 / 4 = .8839$  or 88.4% utilization rate

By the end of FY2, DC Hoke is projected to have:

- 103.81 patients/28 certified stations = 3.71 patients/station [ $103.81/28=3.71$ ]
- $3.71 / 4 = .9286$  or 92.9% utilization rate

**Access to Medically Underserved Groups**

In Section C, page 31, the applicant states:

*“The facility will serve patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability and socioeconomic groups of patients in need of dialysis.”*

The applicant provides the estimated percentage 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	94.8%
Racial and ethnic minorities	90.1%
Women	42.3%
Persons with Disabilities	100%
Persons 65 and older	54.9%
Medicare beneficiaries	87.0%
Medicaid recipients	6.5%

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services. DC Hoke is an existing dialysis facility in Hoke County currently providing services to medically underserved groups.

**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.

- (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

Dialysis Care of Hoke County proposes to add no more than 3 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 28 stations upon project completion.

In Section E, page 41, 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. This alternative was dismissed given the growth rate at the facility.
- Relocate stations from another DaVita facility. Of the two other DaVita facilities in Hoke County, one is operating at less than 75% capacity. Relocating stations from Lumbee River Dialysis would negatively impact the patients presently served by this facility given they operate three days a week to meet the needs of their patients, the scheduling requirements of the physicians, and to maximize staffing efficiencies.

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

- Adding the three stations will avoid higher utilization rates that can potentially interrupt patient services.
- 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
- Information publicly available during the review and used by the Agency

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

- 1. Total Renal Care of North Carolina, LLC. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. Pursuant to Condition 2 of the facility need determination in the 2023 SMFP, the certificate holder shall develop no more than three additional in-center dialysis stations for a total of no more than 28 in-center stations at Dialysis Care of Hoke County.**

### 3. Progress Reports

- a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.
  - b. The certificate holder shall complete all sections of the Progress Report form.
  - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.
  - d. The first progress report shall be due on May 1, 2024.
4. 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

Dialysis Care of Hoke County proposes to add no more than 3 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 28 stations upon project completion.

#### **Capital and Working Capital Costs**

In Section Q, Form F.1a, page 91, the applicant projects the total capital cost of the project, as shown in the table below.

<b>Total Renal Care of North Carolina, LLC Capital Costs</b>	
Medical Equipment	\$30,000
Non-Medical Equipment	\$12,080
Furniture	\$ 6,000
<b>Total</b>	<b>\$48,080</b>

In Section Q, page 92, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on the cost of what is required to add the three additional stations. The applicant states that this includes furniture, fixtures, and equipment needed to accommodate the proposed expansion.

In Section F, page 44, the applicant states that there will be no start-up or initial operating expenses associated with the proposed project because Dialysis Care of Hoke County is an existing facility.

**Availability of Funds**

In Section F, page 43, the applicant states that the capital cost will be funded, as shown in the table below.

**Sources of Capital Cost Financing**

Type	Total Renal Care of North Carolina, LLC	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$48,080	\$48,080
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$48,080	\$48,080

\* OE = Owner's Equity

Exhibit F contains a letter from the Chief Accounting Officer for DaVita Kidney Care, parent company to Total Renal Care of North Carolina, LLC, stating its commitment to fund the project through its cash reserves. Exhibit F also contains DaVita's 2022 consolidated balance sheets stating there are over \$244 million in cash and cash equivalents and over \$15 billion in assets to fund the project.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the information provided in Exhibit F.

**Financial Feasibility**

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

Dialysis Care of Hoke County	1 <sup>st</sup> FFY CY 2025	2 <sup>nd</sup> FFY CY 2026
Total Treatments	14,417	15,056
Total Gross Revenues (Charges)	\$4,147,557	\$4,332,243
Total Net Revenue	\$4,010,391	\$4,188,001
Average Net Revenue per Treatment	\$278	\$278
Total Operating Expenses (Costs)	\$2,918,943	\$3,015,471
Average Operating Expense per Treatment	\$262	\$260
Net Income	\$1,091,448	1,172,530

From Form F. 2 and F.3.

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

- The applicant provides reasonable assumptions in determining revenue and operating expenses in preparation of Form F.2, F.3 and F.4.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

### C

Dialysis Care of Hoke County proposes to add no more than 3 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 28 stations upon project completion.

On page 113, the 2023 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located.*” Thus, the service area for this facility consists of Hoke County. Facilities may also serve residents of counties not included in their service area.

The table below lists the existing and approved facilities, certified stations, and utilization of dialysis facilities in Hoke County as of December 31, 2022, as reported in the 2024 Proposed

SMFP. There are three kidney disease treatment centers providing dialysis services in Hoke County.

Hoke County

Facility Name	Certified Stations as of 12/31/2022	#IC Patients as of 12/31/2022	Utilization by Percent as of 12/31/2022	Patients Per Station Per Week as of 12/31/2022	Number of Additional Stations Approved
Dialysis Care of Hoke County	25	77	77.00%	3.08	1
Fayetteville Road Dialysis	19	67	88.16%	3.52632	11
Lumbee River Dialysis	15	27	45.00%	1.8	0
<b>Total</b>	<b>59</b>	<b>171</b>	<b>72.46%</b>		

Source: Proposed 2024 SMFP, Table 9A, page 123

In Section G, page 50, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Hoke County. The applicant states:

*“While adding stations at this facility does increase the number of stations in Hoke 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 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 adequately demonstrates that the proposed dialysis stations are needed in addition to the existing or approved dialysis stations.
- There is a facility need determination in the 2023 SMFP for six dialysis stations at DC Hoke.

**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

In Section, Q, page 100, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as ed in the following table:

Position	Current FTE Staff	Projected FTE Staff	Projected FTE Staff
	As of 6/30/23	1 <sup>st</sup> Full Fiscal Year	2 <sup>nd</sup> Full Fiscal Year
Administrator	1.00	1.00	1.00
Registered Nurses (RNs)	3.25	3.50	3.50
Licensed Practical Nurses (LPNs)	0.00	0.00	0.00
Home Training Nurse	0.00	0.00	0.00
Technicians (PCT)	9.50	10.50	10.50
Medical Records	0.00	0.00	0.00
Dietician	1.00	1.00	1.00
Social Worker	1.00	1.00	1.00
Housekeeping	0.00	0.00	0.00
Maintenance	0.00	0.00	0.00
Administration/Business Office	1.00	1.00	1.00
Other (Biomedical Tech)	0.50	0.50	0.50
<b>TOTAL</b>	<b>17.25</b>	<b>18.50</b>	<b>18.50</b>

The assumptions and methodology used to project staffing are provided in Section Q, page 100. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.4. In Section H, pages 53- 54, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

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

- The facility is an existing facility, and the applicant bases its staffing on its historical experience providing dialysis services at the facility.
- The applicant has existing policies in regard to recruitment, 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.

C

Dialysis Care of Hoke County proposes to add no more than 3 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 28 stations upon project completion.

**Ancillary and Support Services**

In Section I, page 56, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 56-58, 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 59, the applicant describes its existing and proposed relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on its established relationships with other physicians and hospitals in the area and its agreements for lab services, hospital affiliation and transplant.

**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.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
  - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
  - (iii) would cost no more than if the services were provided by the HMO; and
  - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

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 68, the applicant provides the historical payor mix during CY2022 for the proposed services, shown in the table below.

<b>DC Hoke County Historical Payor Mix 01/01/2022-12/31/2022</b>		
<b>Payor Source</b>	<b>In-Center Dialysis</b>	
	<b># of Patients</b>	<b>% of Total</b>
Self-Pay	1	1.3%
Insurance*	3	3.9%
Medicare*	67	87.0%
Medicaid*	5	6.5%
Other - VA	1	1.3%
<b>Total</b>	<b>77</b>	<b>100.0%</b>

\* Including any managed care plans.

Source: Section L, page 68

In Section L, page 69, the applicant provides the following comparison.

<b>DC Hoke County</b>	<b>Percentage of Total Patients Served</b>	<b>Percentage of the Population of the Service Area *</b>
Female	42.3%	50.9%
Male	57.7%	49.1%
Unknown	0.0%	0.0%
64 and Younger	45.1%	88.3%
65 and Older	54.9%	11.7%
American Indian	4.2%	8.5%
Asian	0.0%	1.7%
Black or African American	85.9%	36.4%
Native Hawaiian or Pacific Islander	0.0%	0.4%
White or Caucasian	9.9%	48.0%
Other Race	0.0%	5.0%
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

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 70, the applicant states

*“...that it 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 70, 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.

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 71, 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.

<b>DC Hoke County Projected Payor Mix 01/01/2026-12/31/2026</b>		
<b>Payor Source</b>	<b>In-Center Dialysis</b>	
	<b># of Patients</b>	<b>% of Total</b>
Self-Pay	1.32	1.3%
Insurance*	3.96	3.9%
Medicare*	88.37	87.0%
Medicaid*	6.60	6.5%
Other -VA	1.32	1.3%
<b>Total</b>	<b>101.56</b>	<b>100.0%</b>

\*Including any managed care plans.

**Source:** Section L, page 71

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 1.3% of total services will be provided to self-pay patients, 87.0% to Medicare patients and 6.5% to Medicaid patients.

On page 71, 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 calculates payor mix based upon treatment volumes as opposed to the number of patients.
- The applicant considers possible change in payor source during the fiscal year.
- Payor mix projections are based on recent facility performance.

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 72, 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

Dialysis Care of Hoke County proposes to add no more than 3 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 28 stations upon project completion.

In section M, page 74, 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 facility has a history of offering health-related education and training programs including visiting the facility to observe the operation of the unit while patients receive treatment.
- The applicant provides a copy of a letter sent to Sandhills Community College – Hoke Center encouraging the school to include Dialysis Care of Hoke County facility in their clinical rotations for nursing students.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

Dialysis Care of Hoke County proposes to add no more than 3 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 28 stations upon project completion.

On page 113, the 2023 SMFP defines the service area for dialysis stations as *“the service area is the county in which the dialysis station is located.”* Thus, the service area for this facility consists of Hoke County. Facilities may also serve residents of counties not included in their service area.

The table below lists the existing and approved facilities, certified stations, and utilization of dialysis facilities Hoke County as of 9A of December 31, 2021.

Hoke County

Facility Name	Certified Stations as of 12/31/2022	#IC Patients as of 12/31/2022	Utilization by Percent as of 12/31/2022	Patients Per Station Per Week as of 12/31/2022	# of additional stations approved
Dialysis Care of Hoke County	25	77	77.00%	3.08	1
Fayetteville Road Dialysis	19	67	88.16%	3.52632	11
Lumbee River Dialysis	15	27	45.00%	1.8%	0
<b>Total</b>	<b>59</b>	<b>171</b>	<b>72.46%</b>		

Source: Proposed 2024 SMFP, Table 9A, page 123

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 76, the applicant states:

*“The expansion of DC Hoke County will have no effect on competition in Hoke County.”*

....

*This project will make it easier for patients, family members and others involved in the dialysis project to receive services.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 76, the applicant states:

*“...with additional capacity, greater operational efficiency is possible which positively impacts costeffectiveness.”*

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

Regarding the impact of the proposal on quality, in Section N, page 76, 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, pages 76 - 77, 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 B, L and C of the application and any exhibits.

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

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant’s representations about how it will ensure the quality of the proposed services.
- 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, pages 101- 104, the applicant identifies the kidney disease treatment facilities located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 109 of this type of facility located in North Carolina.

In Section O, page 79, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to immediate jeopardy have occurred in any of these facilities. After reviewing and considering information provided by the applicant and considering the quality of care provided at all 109 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

## 10A NCAC 14C .2203 PERFORMANCE STANDARDS

a) *An applicant proposing to establish a new dialysis facility for in-center hemodialysis services shall document the need for at least 10 dialysis stations based on utilization of 2.8 in-center patients per station per week as of the end of the first full fiscal year of operation following certification of the facility. An applicant may document the need for fewer than 10 stations if the application is submitted in response to an adjusted need determination in the State Medical Facilities Plan for fewer than 10 stations.*

-NA- The applicant is not proposing to establish a new dialysis facility.

(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 28 and Section Q, page 88, the applicant projects that DC Hoke County will serve 99 in-center patients on 28 stations, or a rate of 3.54 patients per station per week, as of 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 is not proposing to establish a new dialysis facility dedicated to home hemodialysis or peritoneal dialysis training.

(d) *An applicant proposing to increase the number of home hemodialysis stations in a dialysis facility dedicated to home hemodialysis or peritoneal dialysis training shall document the need for the total number of home hemodialysis stations in the facility based on training six home hemodialysis patients per station per year as of the end of the first full fiscal year of operation following certification of the additional stations.*

-NA- The applicant is not proposing to increase the number of home hemodialysis stations in a dialysis facility dedicated to home hemodialysis or peritoneal dialysis training.

(e) *The applicant shall provide the assumptions and methodology used for the projected utilization required by this Rule.*

- C- In Section C, pages 27-28, and Section Q, pages 87-88, the applicant provides the assumptions and methodology it uses to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.