

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: September 11, 2023

Findings Date: September 11, 2023

Project Analyst: Crystal Kearney

Co-Signer: Mike McKillip

Project ID #: J-12406-23

Facility: Durham Regional Dialysis

FID #: 160396

County: Durham

Applicant(s): DVA Healthcare Renal Care, Inc.

Project: Add no more than 10 dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 20 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

DVA Healthcare Renal Care, Inc. (hereinafter referred to as “the applicant” or “Durham Regional Dialysis”) proposes to add no more than 10 dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 20 stations upon project completion.

Need Determination (Condition 1)

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 9C, on page 135 of the 2023 SMFP, the county need methodology shows there is not a county need determination for additional dialysis stations in Durham County.

However, the applicant is eligible to apply for additional dialysis stations in an existing facility pursuant to Condition 1 of the facility need methodology in the 2023 SMFP, if the facility is a “new,” “small,” or “new and small” facility as defined in the 2023 SMFP, and if the facility’s current reported utilization is at least 75%, or 3.0 patients per station in a given week. “Current” means in-center utilization as of a reporting date no more than 90 days before the date the certificate of need application is submitted. If applying pursuant to Condition 1, the facility may only apply once during the calendar year.

In Section B, page 19, the applicant reports the following:

Facility Need Methodology Condition 1 (New and Small Facilities Only)	Response
Number of months the facility had been certified as of the data cut-off date in the SMFP	49
Number of stations in the facility as of the data cut-off date in the SMFP	10
According to Table 9A in the & SMFP, the facility is designated as new, small, or new and small	Small
Number of stations proposed in this application	10
Number of in-center patients per station as of the current reporting date	3.4
Current Reporting Date (no more than 90 days before the application is submitted)	05/31/2023
Previous Reporting Date (six months prior to the Current Reporting Date)	11/30/2022

Application of the facility need methodology for Condition 1 indicates that up to a potential maximum of 10 additional stations are needed at this facility, as illustrated in the following table.

1	# of In-center Patients as of the Current Reporting Date *	34
2	# of In-Center Patients as of the Previous Reporting Date **	24
3	Subtract Line 2 from Line 1 (Net In-center Change for 6 Months)	10
4	Divide Line 3 by Line 2 (6-month Growth Rate)	0.4
5	Multiply Line 4 by 2 (Annual Growth Rate)	0.8
6	Multiply Line 5 by Line 1 (New Patients)	28.3
7	Add Line 6 to Line 1 (Total Patients)	62.3
8	Divide Line 7 by 2.8 (Total # of Stations Needed)	22.3
9	# of Stations as of the Application Deadline^	10.0
10	Subtract Line 9 from Line 8 (Additional Stations Needed)	12.3

* Current Reporting date should be no more than 90 days before the date the CON application was submitted.

** Previous Reporting date is six months prior to the Current Reporting date.

^ Includes all stations that were: 1) certified; 2) CON approved but not yet certified; and 3) proposed to be added in applications still under review as of the application deadline.

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is 12, based on rounding allowed in Condition 1.b.(vii). Condition 1.c of the facility need methodology states, “*The facility may apply for any number of stations up to the number calculated in Condition 1.b.vii, up to a maximum of 10 stations.*” Durham Regional Dialysis proposes to add ten new stations; therefore, the application is consistent with Condition 1 of the facility need determination for dialysis stations.

Policies

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

Durham Regional Dialysis describes how it believes the proposed project will promote safety and quality in Section B.7 (a) and (d), pages 20 and 22, 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

Durham Regional Dialysis describes how it believes the proposed project will promote equitable access in Section B.7 (b) and (d), pages 21-22, Section L, pages 68-72; 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

Durham Regional Dialysis describes how it believes the proposed project will maximize healthcare value in Section B.7 (c) and (d), page 22; Section N.2(a), page 76; and referenced exhibits. The information provided by the applicant with regard to its efforts to maximize healthcare value 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 1 of the facility need methodology as applied from the 2023 SMFP.
 - The applicant adequately demonstrates how Durham Regional Dialysis 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.
- (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

Durham Regional Dialysis proposes to add ten dialysis stations pursuant to Condition 1 of the facility need methodology for a total of twenty stations upon project completion.

Patient Origin

On page 113, the 2023 SMFP defines the service area for dialysis stations as “...*the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” Thus, the service area for this facility consists of Durham County. Facilities may serve residents of counties not included in their service area.

The following table illustrates historical and projected patient origin.

County	Durham Regional Dialysis Patient Origin			
	Historical Last Full FY CY 2022		Projected 2 nd Full FY CY 2026	
	# of Patients	% of Total	# of Patients	% of Total
Durham	22	81.5%	62.6628	91.3%
Granville		0.0%	2	2.9%
Vance	1	3.7%	1	1.5%
Other States	4	14.8%	3	4.4%
Total	27	100.0%	68.6628	100.0%

Source: Section C, pages 25 - 26

The applicant does not currently provide home peritoneal dialysis and home hemodialysis and does not project to begin offering those services in this application.

In Section C, pages 26-27, and immediately following Form C in Section Q, 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 at Durham Regional Dialysis.

Analysis of Need

In Section C, pages 28-29, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 28, the applicant states:

“In Section C, Question 3 we demonstrate that an additional 10 stations will be well utilized by the population to be served, the current and projected in-center patients of Durham Regional 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 1 of the facility need methodology, as stated in the 2023 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.

Projected Utilization

In Section Q, Form C Utilization, page 87, the applicant provides the assumptions and methodology. The applicant states:

“Projections for patient utilization begin with the patient population at Durham Regional Dialysis as of May 31, 2023. The census as of the current reporting date included 34 in-center patients. Of these 34 patients, 28 lived in the service area, Durham County, and 6 lived outside of the service area.”

The first full FY is projected to begin January 1, 2025, and end on December 31, 2025.

The second full FY is projected to begin January 1, 2026, and end on December 31, 2026.

While the Average Annual Change Rate for the Past Five Years (5YAACR) as indicated in Table 9B of the 2023 SMFP for the in-center patients living in Durham County was 0.3%, the facility’s growth has been significantly higher.”

On page 27, the applicant provided the following table showing the year-end patient census and annual growth rates at Durham Regional Dialysis from CY2018 through CY2022.

Year Ending	In-center census	Percent Change
12/31/2018	12	
12/31/2019	26	116.7%
12/31/2020	21	19.2%
12/31/2021	18	14.3%
12/31/2022	27	50.0%
5 Year AACR		33.3%

On page 27, the applicant states,

“The following in-center patient projections apply a growth rate of 25.0% for the in-center patients living in Durham County, so as to be conservative. The period of the growth begins June 1, 2023, and is calculated forward to December 31, 2026. No growth calculations were performed for the patients living outside of Durham County”.

In Section Q, page 88, the applicant provides the calculations used to project the patient census for FY1 and FY2, as summarized in the table below.

	IC Stations	IC Patients
The applicant begins with the 34 patients dialyzing on 10 stations at the facility as of 5/31/2023.	10	34
The facility's Durham County patient census is projected forward seven months from 06/01/2023 forward to 12/31/2023 and is increased by 7/12 the growth rate of 25.0%.		$28 \times 1.146 = 32.08333$
The 6 patients from outside Durham County are added to the facility's census. This is the ending census as of Interim Year 1.		$32.08 + 6 = 38.08$
The facility's Durham County patient census is projected forward a year to 12/31/2024 and is increased by 25.0%		$32.08 \times 1.25 = 40.10417$
The 6 patients from outside Durham County are added to the facility's census. This is the ending census for the second full interim year		$40.10 + 6 = 46.10$
The proposed project is projected to be certified on 1/1/2025. This is the station count at the beginning of the project's first full fiscal year (FY1). The facility's Durham County patient census is projected forward a year to 12/31/2025 and is increased by 25.0%	$10 + 10 = 20$	$40.10 \times 1.25 = 50.13021$
The 6 patients from outside Durham County are added to the facility's census. This is the ending census for FY1.		$50.13 + 6 = 56.13$
The facility's Durham County patient census is projected forward a year to 12/31/2026 and is increased by 25.0%		$50.13 \times 1.25 = 62.66276$
The 6 patients from outside Durham County are added to the facility's census. This is the ending census as of the project's second full fiscal year (FY2).		$62.66 + 6 = 68.66$

Projected patients for FY1 and FY2 are rounded to the nearest whole number.

Based on the calculations above, by the end of FY1 Durham Regional Dialysis is projected to have:

- 56 patients / 20 certified stations = 2.8 patients / station
- $2.8 / 4 = 0.70$ or 70.0% utilization rate

By the end of FY2, Durham Regional Dialysis is projected to have:

- 69 patients / 20 certified stations = 3.45 patients / station
- $3.45 / 4 = 0.8625$ or 86.25 % utilization rate

The applicant projects to serve 56 patients on 20 stations, which is 2.8 patients per station per week ($56 \text{ patients} / 20 \text{ stations} = 2.8$), which meets the minimum of 2.8 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

Projected utilization is reasonable and adequately supported for the following reasons:

- The applicant was operating at a rate of 3.4 patients per station per week, or 85% of capacity, on May 31, 2023.
- The applicant projects future utilization based on historical utilization.
- Even though the applicant projects a higher growth rate for its patient population than the Durham County 5-year AACR as published in the 2023 SMFP, it uses a projected growth rate that is lower than its recent historical growth rate.

Access to Medically Underserved Groups

In Section C, page 31, the applicant states:

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

The applicant provides the estimated percentage of the total patients for each medically underserved group during the second full fiscal year, as shown in the following table.

Medically Underserved Groups	Estimated Percentage of Total Patients during the Second Full Fiscal Year
Low income persons	77.8%
Racial and ethnic minorities	77.8%
Women	55.5%
Persons with disabilities	100%
Persons 65 and older	48.1%
Medicare beneficiaries	66.7%
Medicaid recipients	11.1%

Source: Section C, page 31.

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 following:

- The applicant provides a statement saying it will provide service to all residents of the service area, including underserved groups, without regard for anything other than the need for dialysis services.
- The applicant states the percentage of patients for each group listed above are based on recent facility experience.

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 services. 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

Durham Regional Dialysis proposes to add ten dialysis stations pursuant to Condition 1 of the facility need methodology for a total of twenty 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. The utilization data as of current reporting period indicates the patient census is trending upward at this facility.
- Relocate stations from another DaVita facility. Of the seven other DaVita facilities in Durham County, four are operating at less than 75% capacity, as reflected in the 2023 SMFP. Three of the four are small facilities and relocating stations from them would result in facilities with fewer than 10 stations. The fourth facility, Durham West Dialysis, offers home hemodialysis training and support services and only utilizes 23 of its 27 stations for in-center patients. Relocating stations would negatively impact this facility's operations and the patients presently served by this facility as it would disrupt patient and teammate scheduling at the facility.

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

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 1. DVA Healthcare Renal Care, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. Pursuant to Condition 1 of the facility need determination in the 2023 SMFP, the certificate holder shall develop no more than ten additional dialysis stations for a total of no more than 20 stations at Durham Regional Dialysis.**
- 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 February 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

Durham Regional Dialysis proposes to add ten dialysis stations pursuant to Condition 1 of the facility need methodology for a total of twenty stations upon project completion.

Capital and Working Capital Costs

In Section F.2, the applicant projects the total capital cost of the project. In Section Q, page, 92, the applicant provides assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is reasonable based on the applicant’s experience developing similar expansions projects.

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 Durham Regional Dialysis is an existing facility.

Availability of Funds

In Section F, page 43, the applicant projects the capital cost of the project, as shown in the table below.

Source of Financing for Working Capital	Amount
Loans	\$0
Accumulated Reserves or OE*	\$ 167,980
Bonds	\$0
Other (Describe)	\$0
Total Financing	\$167,980

*OE= Owner’s Equity

Source: Section F, page 43

In Exhibit, F.2, the applicant provides DaVita’s consolidated balance sheet from the U.S. Securities and Exchange Commission Form 10-K for the fiscal year ended December 31, 2022, which indicates the applicant has sufficient funds for the proposed project. In Exhibit F2, a letter dated June 26, 2023, from Chief Accounting Officer of DaVita Kidney Care, the parent company of the applicant, confirming that DaVita is willing to commit cash reserves for the capital cost of the proposed project.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the documentation provided in Exhibit F-2.

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.

	1st FFY CY 2025	2nd FFY CY 2026
Total Treatments	9,461	9,701
Total Gross Revenues (Charges)	\$2,789,001	\$2,859,564
Total Net Revenue	\$2,583,535	\$2,648,901
Average Net Revenue per Treatment	\$273	\$273
Total Operating Expenses (Costs)	\$2,193,582	\$2,246,453
Average Operating Expense per Treatment	\$232	\$232
Net Income	\$389,953	\$402,448

Source: Section Q, Form F.2 Income Statement, page 92.

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 the 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

Durham Regional Dialysis proposes to add ten dialysis stations pursuant to Condition 1 of the facility need methodology for a total of twenty stations upon project completion.

The 2023 SMFP, page 113, 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 Durham County. Facilities may also serve residents of counties not included in their service area.

The table below lists the existing and approved facilities, certified station, and utilization of dialysis facilities in Durham County December 31, 2021. There are thirteen kidney disease treatment centers providing dialysis services in Durham County.

Durham County Dialysis Facilities

	Certified Stations as of 12/31/2022	Number of IC Patients as of 12/31/2022	Utilization by Percent as of 12/31/2022
Bull City Dialysis	20	67	83.75%
Downtown Durham Dialysis	10	19	47.50%
Durham Dialysis	29	89	76.72%
Durham Regional Dialysis	10	27	67.50%
Durham West Dialysis	27	73	67.59%
FMC Dialysis Services of Briggs Avenue	29	92	79.31%
FMC Dialysis Services West Pettigrew	24	52	54.17%
Freedom Lake Dialysis Center	26	49	47.12%
Fresenius Kidney Care Eno River ^	14	46	82.14%
FMC South Durham Dialysis	20	75	93.73%
Hope Valley Dialysis	10	20	50.00%
Research Triangle Park Dialysis	10	18	45.00%
Southpoint Dialysis	16	62	96.8%

Source: 2023 SMFP, Table 9A, pages 121-122.

In Section G, page 51, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Durham County. The applicant states:

“While adding stations at this facility does increase the number of stations in Durham 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 in Durham County based on Condition 1 of the facility need determination methodology in the 2023 SMFP.
- The applicant adequately demonstrates that the proposed dialysis stations are needed in addition to the existing or approved dialysis station.

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

Durham Regional Dialysis proposes to add ten dialysis stations pursuant to Condition 1 of the facility need methodology for a total of twenty stations upon project completion.

In Section Q, Form H, page 99, 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	Projected FTE Staff
	As of 2/28/2023	1 st Full FY	2 nd Full FY
Administrator	1.00	1.00	1.0
Registered Nurses (RNs)	2.00	3.00	3.0
Licensed Practical Nurses (LPNs)	0.00	0.00	0.00
Home Training Nurse	0.00	0.00	0.00
Technicians (PCT)	6.00	8.75	8.75
Medical Records	0.00	0.00	0.00
Dietician	0.50	0.50	0.50
Social Worker	0.50	0.50	0.50
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
TOTAL	11.50	15.25	15.25

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 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

Durham Regional Dialysis proposes to add ten dialysis stations pursuant to Condition 1 of the facility need methodology for a total of twenty 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 56-59, 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 several healthcare providers and social service agencies in the county.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered.

- (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 I, page 68, the applicant provides the historical payor during CY 2022 for the proposed services, as shown in the table below.

Durham Regional Dialysis Historical Payor Mix 01/01/2022-12/31/2022		
Payor Source	In-Center Dialysis	
	# of Patients	% of Total
Self-Pay	0.0	0.00%
Insurance*	4.0	14.8%
Medicare*	18.0	66.7%
Medicaid*	3.0	11.17%
Other-VA	2.0	7.4%
Total	27.0	100.0%

*Including any managed care plans.
 Source: Section L, page 68

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

Durham Regional Dialysis	Percentage of Total Patients Served	Percentage of the Population of the Service Area*
Female	55.6%	52.2%
Male	44.4%	47.8%
Unknown		
64 and Younger	51.9%	85.7%
65 and Older	48.1%	14.3%
American Indian	0.0%	1.0%
Asian	0.0%	5.3%
Black or African American	77.8%	35.9%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	22.2%	54.5%
Other Race	0.0%	2.8%
Declined / Unavailable	0.0%	0.0%

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

The Agency reviewed the:

- Application
- Exhibits to the application
- 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:

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

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

- (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.

Durham Regional Dialysis Projected Payor Mix 01/01/2026-12/31/2026		
Payor Source	In-Center Dialysis	
	# of Patients	% of Total
Insurance*	10.17	14.8%
Medicare*	45.78	66.7%
Medicaid*	7.63	11.1%
Other-VA	5.09	7.4%
Total	68.66	100.0%

*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 to provide 66.7% of total dialysis services to Medicare patients and 11.1% of total dialysis services to Medicaid patients.

On pages 71-72, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical (CY2022) payor mix at Durham Regional Dialysis.

The Agency reviewed the:

- Application
- Exhibits to the application

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

Durham Regional Dialysis proposes to add ten dialysis stations pursuant to Condition 1 of the facility need methodology for a total of twenty stations upon project completion.

In Section M, page 75, 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 allowing health-related education and training programs visit the facility to observe the operation of the unit while patients receive treatment.
- The applicant provides a copy of a letter sent to Durham Technical Community College encouraging the school to include facility in their Durham Regional Dialysis 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

Durham Regional Dialysis proposes to add ten dialysis stations pursuant to Condition 1 of the facility need methodology for a total of twenty 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 Durham 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 Durham County as of December 31, 2022. There are thirteen kidney disease treatment centers providing dialysis services in Durham County.

Durham County Dialysis Facilities

	Certified Stations as of 12/31/2022	Number of IC Patients as of 12/31/2022	Utilization by Percent as of 12/31/2022
Bull City Dialysis	20	67	83.75%
Downtown Durham Dialysis	10	19	47.50%
Durham Dialysis	29	89	76.72%
Durham Regional Dialysis	10	27	67.50%
Durham West Dialysis	27	73	67.59%
FMC Dialysis Services of Briggs Avenue	29	92	79.31%
FMC Dialysis Services West Pettigrew	24	52	54.17%
Freedom Lake Dialysis Center	26	49	47.12%
Fresenius Kidney Care Eno River ^	14	46	82.14%
FMC South Durham Dialysis	20	75	93.73%
Hope Valley Dialysis	10	20	50.00%
Research Triangle Park Dialysis	10	18	45.00%
Southpoint Dialysis	16	62	96.8%

Source: 2023 SMFP, Table 9A, pages 121-122.

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

“The expansion of Durham Regional Dialysis will have no effect on competition in Durham County....The expansion of Durham Regional Dialysis will enhance accessibility to dialysis for our patients, and by reducing the economic and physical burdens on our patients, this project will enhance the quality and cost effectiveness of our services because it will make it easier for patients, family members and others involved in the dialysis process to receive services.

The bottom line is Durham Regional 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 76, the applicant states:

“The expansion of Durham Regional 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 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:

“As discussed in Section B and Section O, DaVita is committed to providing quality care to the ESRD population and, by policy, works to make every reasonable effort to accommodate all of its patients.”

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 77, the applicant states:

“It is corporate policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, or any other factor that would classify a patient as underserved.”

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

Durham Regional Dialysis proposes to add ten dialysis stations pursuant to Condition 1 of the facility need methodology for a total of twenty stations upon project completion.

In Section Q, Form O, 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 82, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to immediate jeopardy has not 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

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.

10A 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 stations based on utilization of 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.

-NA- Durham Regional Dialysis is an existing facility. The applicant does not propose to establish a new kidney disease treatment center or dialysis facility. Therefore, this performance standard is not applicable to this review.

(b) An applicant proposing to increase the number of dialysis stations in:
(1) an existing dialysis facility; or
(2) a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need;

shall document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the additional stations.

-C- In Section C, page 27 and on Form C in Section Q, page 88, the applicant projects to serve 56 patients on 20 stations, which is 2.8 patients per station per week (56 patients/20 stations= 2.8) , by the end of OY1 and 68 patients on 20 stations, which is 3.4 patients per station per week (56 patients/20 stations = 3.4). by the end of OY2. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

(c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.

-C- In Section C, pages 27, and Section Q, pages 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.