

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: August 25, 2023

Findings Date: August 25, 2023

Project Analyst: Tanya M. Saporito

Co-Signer: Gloria C. Hale

Project ID #: O-12343-23

Facility: Leland Dialysis

FID #: 140237

County: Brunswick

Applicant: Total Renal Care of North Carolina, LLC

Project: Add no more than seven dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 23 stations upon project completion

REVIEW CRITERIA

G.S. 131E-183(a): The Agency shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C

Total Renal Care of North Carolina, LLC (hereinafter "TRC" or "the applicant") proposes to add seven stations to Leland Dialysis pursuant to Condition 2 of the facility need methodology for a total of 23 in-center dialysis stations upon project completion.

Need Determination

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, page 135, the county need methodology shows there is no county need determination for additional dialysis stations in Brunswick 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 dialysis center 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. Table 9A on page 119 of the 2023 SMFP shows the utilization rate reported for Leland Dialysis is 82.81% or 3.31 patients per station per week based on 53 in-center dialysis patients and 16 certified dialysis stations (53 patients / 16 stations = 3.31; $3.31 / 4 = 82.81\%$).

As shown in Table 9D on page 136 of the 2023 SMFP, based on the facility need methodology for dialysis stations, the potential number of stations needed at Leland Dialysis is up to seven additional stations; thus, the applicant is eligible to apply to add up to seven stations during the 2023 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than seven new stations to Leland Dialysis, which is consistent with the 2023 SMFP calculated facility need determination for up to seven dialysis 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 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.”

In Section B, pages 20-22, the applicant explains why it believes its application is consistent with Policy GEN-3. On page 20, the applicant states:

“DaVita’s goal is to create a ‘Culture of Safety’ in all of its facilities and to make this a core part of how we function. The primary components of a culture of safety are a robust and proactive system for reporting and addressing errors, open blame-free communication between all levels of staff and patients, communication of clear expectations of staff, and complete staff and patient engagement to assure that everyone at the facility is committed to identifying and mitigating any risks to patients. ...”

Promote Safety and Quality

The applicant describes how it believes the proposed project will promote safety and quality in Section B, pages 20-21; Section N, page 75; Section O, pages 78-80; 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 to dialysis services in Section B, page 21; Section C, pages 30-31; Section L, pages 70-71 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 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 Leland Dialysis'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.

(2) Repealed effective July 1, 1987.

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

C

The applicant proposes to add seven dialysis stations to Leland Dialysis pursuant to Condition 2 of the facility need methodology for a total of 23 in-center stations following project completion.

In Section C, page 28, the applicant documents that Leland Dialysis does not currently provide home hemodialysis (HH) and home peritoneal dialysis (PD) training and support.

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. 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 Brunswick County. Facilities may serve residents of counties not included in their service area.

The following tables, from Section C, pages 25-26, illustrate historical patient origin from calendar year (CY) 2022, and projected patient origin for the second full project year (PY), CY 2026 at Leland Dialysis:

Leland Dialysis Historical Patient Origin, CY 2022

COUNTY	# IN-CENTER PTS.	% OF TOTAL
Brunswick	50	83.3%
Bladen	2	3.3%
Columbus	4	6.7%
New Hanover	3	5.0%
Pender	1	1.7%
Total	60	100.0%

Numbers may not sum due to rounding
Source: application page 25

Leland Dialysis Projected Patient Origin, CY 2026

COUNTY	# IN-CENTER PTS.	% OF TOTAL
Brunswick	56.2754	84.9%
Bladen	2	3.0%
Columbus	4	6.0%
New Hanover	3	4.5%
Pender	1	1.5%
Total	66.2754	100.0%

Numbers may not sum due to rounding
Source: application page 26

In Section C, pages 26-27, and *Form C Utilization* in application Section Q, the applicant provides the assumptions and methodology used to project patient origin. The applicant's assumptions are reasonable and adequately supported based on the following:

- The applicant's projections are based on the historical patient origin at Leland Dialysis.
- The applicant projected growth in the patient population of the home county, Brunswick County, and did not project growth in the patient population residing outside of Brunswick County.

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. The applicant states:

“There is a facility need determination of 7 stations for Leland Dialysis which has 16 existing stations, as reported in Tables 9D and 9A of the 2023 SMFP. In Section C, Question 3 we demonstrate that an additional 7 stations will be well utilized by the population to be served, the current and projected in-center patients of Leland 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 for the following reasons:

- According to Table 9A on page 119 of the 2023 SMFP, Leland Dialysis was operating at a rate of 3.31 patients per station per week, or 82.81% of capacity as of December 31, 2021.
- Table 9D on page 136 of the 2023 SMFP shows Leland Dialysis has a need for seven additional in-center dialysis stations.
- The applicant demonstrates the need for the additional seven stations using the Brunswick County Five Year Average Annual Change Rate of 3.0%.

Projected Utilization

In Section C, pages 26-27, and in “*Form C Utilization-Criterion (3)*”, the applicant provides the assumptions and methodology used to project patient utilization, which are summarized below:

- The applicant begins its utilization projections with the patient census on December 31, 2022, at which point the in-center patient census was 60 in-center patients, including 50 Brunswick County patients and ten patients from outside the service area.

- The Brunswick County Average Annual Change Rate (AACR) as published in the 2023 SMFP is 3.0%. The applicant applies this AACR to the Brunswick County patient population to project future patient growth.
- The applicant assumes no population growth for the patients residing outside of Brunswick County who are dialyzing at Leland Dialysis but assumes the patients will continue to dialyze at that facility and adds them to the calculations as appropriate.
- The first project year is projected to be CY 2025 and the second project year is projected to be CY 2026.

In Section C, page 27, the applicant provides the calculations used to project the patient census for PY1 and PY2, as summarized in the following table:

Leland Dialysis Projected Utilization Calculations		
LELAND DIALYSIS	# IN-CTR. STATIONS	# IN-CTR. PTS.
Begin with 60 in-center patients dialyzing on 16 stations as of 12/31/22	16	60
Project Brunswick County patients forward one year using Brunswick County Five Year AACR		$50 \times 1.030 = 51.50$
Add 10 patients from outside Brunswick County		$51.50 + 10 = 61.50$
Project Brunswick County patients forward one year using Five Year AACR		$51.50 \times 1.030 = 53.045$
Add 10 patients from outside Brunswick County		$53.05 + 10 = 63.05$
Projected certification for facility; add seven stations and project patient population forward one year using Five Year AACR	$16 + 7 = 23$	$53.05 \times 1.030 = 54.636$
Add 10 patients from outside Brunswick County. This is end of PY 1		$54.64 + 10 = 64.64$
Project Brunswick County patients forward one year using Five Year AACR		$54.64 \times 1.030 = 56.275$
Add 10 patients from outside Brunswick County. This is end of PY 2		$56.28 + 10 = 66.28$

As shown in the table above, the applicant projects to serve 65 patients on 23 stations, which is 2.8 patients per station per week ($65 \text{ patients} / 23 \text{ stations} = 2.8$) by the end of PY1. By the end of PY 2, the applicant projects to serve 66 patients on 23 stations, which is 2.9 patients per station per week ($66 \text{ patients} / 23 \text{ stations} = 2.87$), by the end of PY 2. This 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).

Access to Medically Underserved Groups

In Section C.6, pages 30-31, the applicant states:

“By policy, the proposed services will be made available to all residents in the service area without qualifications. The facility will serve patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability and socioeconomic groups of patients in need of dialysis.”

We will make every reasonable effort to accommodate all patients, especially those with special needs such as those with disabilities, patients attending school or patients who work. Dialysis services will be provided six days per week with two patient shifts per day to accommodate patient need.

Leland 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 total patients for each medically underserved group during the second full fiscal year, as shown in the following table.

MEDICALLY UNDERSERVED `GROUPS	ESTIMATED % OF TOTAL PATIENTS IN 2 ND FY
Low-income persons	91.7%
Racial and ethnic minorities	55.4%
Women	35.7%
Persons with disabilities	100.0%
Persons 65 and older	62.5%
Medicare beneficiaries	80.0%
Medicaid recipients	10.0%

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 percentages of patients for each group listed above are based on the facility’s historical 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 service. Therefore, Criterion (3a) is not applicable to this review.

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

The applicant proposes to add seven dialysis stations to Leland Dialysis pursuant to Condition 2 of the facility need methodology for a total of 23 in-center stations following project completion.

In Section E, page 40, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the status quo – The applicant states maintaining the status quo is not an effective alternative, given the growth rate at the facility.
- Relocate stations from another DaVita facility – The applicant considered relocating stations from another Brunswick County DaVita facility; however, the applicant states that alternative would not fully meet the need at Leland Dialysis and would negatively impact patients currently served because of the scheduling requirements of both patients and physicians. Therefore, this is not an effective alternative.

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, considering the unique needs of this facility and its patients and physicians as well as other Brunswick County DaVita facilities.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 1. Total Renal Care of North Carolina, LLC (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
 - 2. Pursuant to Condition 2 of the facility need determination in the 2023 SMFP, the certificate holder shall develop no more than seven additional in-center dialysis stations for a total of no more than 23 in-center dialysis stations at Leland Dialysis upon project completion.**
 - 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 December 1, 2023.**
 - 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.

The applicant proposes to add seven dialysis stations to Leland Dialysis pursuant to Condition 2 of the facility need methodology for a total of 23 in-center stations following project completion.

Capital and Working Capital Costs

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

Site Costs	\$29,000
Construction Costs	\$726,154
Miscellaneous Costs	\$243,792
Total	\$998,946

In “*Form I.A – Capital Cost/Form F.1B Capital Cost ... Assumptions*”, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant describes the project management team and its expertise with dialysis projects.
- The applicant provided the individual and combined cost of each item that makes up the projected capital cost.

In Section F, page 43, the applicant states there are no start-up costs or initial operating expenses associated with the project. The facility is an existing facility that is currently operational.

Availability of Funds

In Section F.2, page 42, the applicant states it will fund the capital cost of the proposed project with accumulated reserves of Total Renal Care of North Carolina, LLC. Exhibit F.2 includes the Consolidated Balance Sheets for DaVita, Inc. for years ending December 31, 2021 and December 31, 2022 that show sufficient assets, including cash and cash equivalents to fund the total project capital cost. Exhibit F.2 also contains a letter signed by the Chief Accounting Officer of DaVita Kidney Care that explains DaVita is the 100% owner of Total Renal Care of North Carolina, LLC that confirms sufficient cash reserves for the project capital cost “*along with any other funds that are necessary for the development of the project*”. The letter also confirms DaVita’s willingness to commit the necessary funds to the project.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the following:

- The applicant provided a letter from an appropriate company official confirming sufficient funds and committing those funds to the proposed project.

- The consolidated balance sheets confirm sufficient funds for the project.

Financial Feasibility

The applicant provides pro forma financial statements for the interim and first two full fiscal years of operation following project completion. In Form F.2 in Section Q, the applicant projects that revenues will exceed operating expenses in the first two full fiscal years (FY), of operation, calendar years (CYs) 2025-2026 following project completion, as shown in the table below:

Financial Feasibility, Leland Dialysis

	1ST FULL FY CY 2025	2ND FULL FY CY 2026
Total # Treatments (From Form C)	9,461	9,701
Total Gross Revenue	\$2,789,001	\$2,859,565
Total Net Revenue	\$2,583,535	\$2,648,901
Net Revenue per Treatment	\$273	\$273
Total Operating Costs	\$2,193,582	\$2,246,453
Operating Costs per Treatment	\$232	\$232
Net Income	\$389,953	\$402,448

The assumptions used by the applicant in preparation of the pro forma financial statements are provided immediately following Form F.2, F.3 and F.4 in Section Q, pages 92-96. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to add seven dialysis stations to Leland Dialysis pursuant to Condition 2 of the facility need methodology for a total of 23 in-center stations following 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. 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 Brunswick County. Facilities may serve residents of counties not included in their service area.

According to Table 9A, page 119 of the 2023 SMFP, there are four existing dialysis facilities in Brunswick County, as shown in the following table:

Brunswick County Dialysis Stations and Utilization, 2023 SMFP

FACILITY	OWNER	LOCATION	# CERTIFIED STATION	UTILIZATION RATE
FMC Brunswick County	BMA^	Supply	10	55.00%
Leland Dialysis	DaVita	Leland	16	82.81%
SEDC-Shallotte*	DaVita	Shallotte	15	58.33%
Southport Dialysis Center	DaVita	Southport	11	63.64%

*SEDC = Southeastern Dialysis Center

^Bio-Medical Applications of North Carolina, Inc.

In Section G, page 49, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Brunswick County. The applicant states:

“Based on the facility need methodology in the 2023 SMFP under Condition 2, Leland Dialysis qualifies to add up to 7 dialysis stations.

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

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

- The applicant proposes to increase the number of dialysis stations in Brunswick County based on Condition 2 of the facility need determination in the 2023 SMFP, which is unique to the Leland Dialysis facility.
- The applicant adequately demonstrates that the proposed dialysis stations are needed in addition to the existing or approved dialysis stations in Brunswick County.

Conclusion

The Agency reviewed the:

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

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

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

C

The applicant proposes to add seven dialysis stations to Leland Dialysis pursuant to Condition 2 of the facility need methodology for a total of 23 in-center stations following project completion.

On Form H in Section Q, the applicant provides current and projected staffing for the proposed services, as illustrated in the following table.

Leland Dialysis Current and Projected Staff

	CURRENT STAFF (2/28/23)	PROJECTED STAFF PYS 1-2
Administrator	1.00	1.00
Registered Nurses	2.00	3.00
Patient Care Technicians	6.00	8.75
Dietician	0.50	0.50
Social Worker	0.50	0.50
Admin/Business Office	1.00	1.00
Bio-Medical Technician	0.50	0.50
Total	11.50	15.25

The assumptions and methodology used to project staffing are provided immediately following Form H in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.4 in Section Q. In Section H, pages 52-53, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

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

- The applicant projects sufficient operating expenses for the staff it proposes.
- The applicant describes the required qualifications for staff, continuing education, and other training programs.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to add seven dialysis stations to Leland Dialysis pursuant to Condition 2 of the facility need methodology for a total of 23 in-center stations following project completion.

Ancillary and Support Services

In Section I, page 55, the applicant identifies the necessary ancillary and support services for the proposed services. In Section I, pages 56-57, 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 based on the following:

- The facility is an existing facility already providing the necessary ancillary and support services.
- The applicant describes the structure in place at both the corporate level and the facility level for providing the necessary ancillary and support services and states those same services will continue to be available following the addition of stations as proposed in this application.

Coordination

In Section I, page 58, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The facility is an existing facility that has existing relationships with local health care and social service providers.
- The applicant provides a letter in Exhibit I from the medical director of the facility attesting to the relationship between the medical director's physician practice and the facility and confirms his commitment to continue to serve as medical director.
- The applicant provides a letter in Exhibit I from the facility Administrator that confirms existing and continuing relationships with local healthcare and social service providers.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

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

NA

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

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

C

The applicant proposes to add seven dialysis stations to Leland Dialysis pursuant to Condition 2 of the facility need methodology for a total of 23 in-center stations following project completion.

In Section K, page 62, the applicant states that the project involves renovating 940 square feet of existing space. Line drawings are provided in Exhibit K.

On pages 62-63, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following:

- The applicant has a real estate department and a development department that oversees facility construction and ensures efficient design.
- The applicant's project management team partners with financial experts to develop the most effective capital cost for the project.
- The applicant implements strategies in existing facilities to maximize energy efficiency, water conservation and sustainability.

On page 63, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the following:

- The applicant's costs to the public of providing the services are based in part on company growth accounted for in its financial statements.
- Some costs are driven by salaries and benefits for its FTEs. The applicant states that additional FTEs are only added when patient census grows, thus keeping facility costs low.
- The applicant states the majority of its patients are covered by Medicare and/or Medicaid and thus the facility is paid based on a single case-mix-adjusted payment. The applicant's capital expenditures for the addition of the dialysis stations proposed in this application are not passed on to its patients.

In Section K, pages 63-64, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit K.3.

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.

- (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 67, the applicant provides the historical payor mix during CY 2022 for its existing services, as shown in the table below.

Leland Dialysis Historical Payor Source CY 2022

PAYOR SOURCE	# IN-CENTER PTS.	% OF TOTAL
Self-Pay	1.00	1.7%
Insurance*	3.00	5.0%
Medicare*	48.00	80.0%
Medicaid*	6.00	10.0%
Other - VA	2.00	3.3%
Total	60.00	100.0%

*Includes managed care plans

In Section L, page 68, the applicant the applicant provides the following comparison:

	PERCENTAGE OF TOTAL PATIENTS SERVED BY LELAND DIALYSIS CY 2022	PERCENTAGE OF THE POPULATION OF BRUNSWICK COUNTY
Female	35.7%	51.9%
Male	64.3%	48.1%
Unknown	0.0%	0.0%
64 and Younger	37.5%	66.7%
65 and Older	62.5%	33.3%
American Indian	0.0%	0.9%
Asian	0.0%	0.8%
Black or African-American	55.4%	9.5%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	44.6%	86.8%
Other Race	0.0%	1.9%
Declined / Unavailable	--	0.0%

Conclusion

The Agency reviewed the:

- Application

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

Based on that review, the Agency concludes that the 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 69, the applicant states it has no such obligation.

In Section L, page 69, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against Leland Dialysis.

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.

- (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 70, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

PAYOR SOURCE	# IN-CENTER PTS.	% OF TOTAL
Self-Pay	1.10	1.7%
Insurance*	3.31	5.0%
Medicare*	53.02	80.0%
Medicaid*	6.63	10.0%
Other - VA	2.21	3.3%
Total	66.28	100.0%

*Includes managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 1.7% of dialysis services will be self-pay, 5.0% will be covered by commercial insurance, 80.0% will be covered by Medicare and 10.0% will be covered by Medicaid.

On page 70, the applicant provides the assumptions and methodology it uses 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 payor mix at Leland Dialysis.

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.

- (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 71, the applicant adequately describes the range of means by which patients will have access to the proposed services.

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.

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

C

The applicant proposes to add seven dialysis stations to Leland Dialysis pursuant to Condition 2 of the facility need methodology for a total of 23 in-center stations following project completion.

In Section M, page 73, 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. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following:

- The applicant provides a copy of a letter previously sent to Brunswick Community College offering the facility as a training site for nursing students.
- Leland Dialysis is an existing facility and currently provides the opportunity for clinical education and training.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to add seven dialysis stations to Leland Dialysis pursuant to Condition 2 of the facility need methodology for a total of 23 in-center stations following 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. 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 Brunswick County. Facilities may serve residents of counties not included in their service area.

According to Table 9A, page 119 of the 2023 SMFP, there are four existing dialysis facilities in Brunswick County, as shown in the following table:

Brunswick County Dialysis Stations and Utilization, 2023 SMFP

FACILITY	OWNER	LOCATION	# CERTIFIED STATION	UTILIZATION RATE
FMC Brunswick County	BMA^	Supply	10	55.00%
Leland Dialysis	DaVita	Leland	16	82.81%
SEDC-Shallotte*	DaVita	Shallotte	15	58.33%
Southport Dialysis Center	DaVita	Southport	11	63.64%

*SEDC = Southeastern Dialysis Center

^Bio-Medical Applications of North Carolina, Inc.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 75, the applicant states:

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

Regarding the impact of the proposal on cost effectiveness, in Section N, page 75, the applicant states:

“The expansion of Leland 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 B, C, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 75 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, pages 75-76, 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, C and L of the application and any exhibits.

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to add seven dialysis stations to Leland Dialysis pursuant to Condition 2 of the facility need methodology for a total of 23 in-center stations following project completion.

On Form O in Section Q, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 109 existing or approved kidney disease treatment facilities located in North Carolina.

In Section O, page 79, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents resulting in an Immediate Jeopardy violation that occurred in any of these facilities. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all 109 facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

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

C

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

10 NCAC 14C .2203 PERFORMANCE STANDARDS

(a) *An applicant proposing to establish a new kidney disease treatment center or dialysis facility shall document the need for at least 10 dialysis stations based on utilization of 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the facility. An applicant may document the need for less than 10 stations if the application is submitted in response to an adjusted need determination in the State Medical Facilities Plan for less than 10 stations.*

-NA- Leland Dialysis is an existing facility. Therefore, this Rule is not applicable to this review.

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

- (1) *an existing dialysis facility; or*
- (2) *a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need;*

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

-C- In Section C, page 27, and on Form C in Section Q, the applicant projects that Leland Dialysis will serve 65 patients on 23 in-center stations, or a rate of 2.83 patients per station per week, as of the end of the first operating year following project completion [65 patients / 23 stations = 2.826]. 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. Therefore, this Rule is not applicable to this review.

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

-NA- 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. Therefore, this Rule is not applicable to this review.

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

-C- In Section C, pages 26-27, and in *Form C Utilization-Criterion (3) in Section Q*, page 86, the applicant provides the assumptions and methodology it used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.