

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: July 2, 2020

Findings Date: July 2, 2020

Project Analyst: Tanya M. Saporito

Team Leader: Gloria C. Hale

Project ID #: O-11881-20

Facility: Leland Dialysis

FID #: 140237

County: Brunswick

Applicant: Total Renal Care of North Carolina, LLC

Project: Add no more than 4 dialysis stations pursuant to facility need for a total of no more than 16 dialysis stations upon project completion

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §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 (the applicant) operates Leland Dialysis in Brunswick County. In this application, the applicant proposes to add no more than four dialysis stations to the existing facility pursuant to the facility need methodology for a total of no more than 16 dialysis stations upon project completion.

Need Determination

Chapter 9 of the 2020 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 9D, page 170, the county need methodology shows there is a not a county need determination for additional dialysis stations for Brunswick 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 2020 SMFP if the facility is a “new” facility or a “small” facility (or both) as defined in the 2020 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. In Section B, page 11, the applicant states it was serving 40 in-center patients on 11 certified stations on its current reporting date of December 31, 2019. This is a utilization rate of 91%, or 3.64 patients per station per week. Table 9B on page 151 of the 2020 SMFP defines Leland Dialysis as a small facility.

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

LELAND DIALYSIS FACILITY NEED METHODOLOGY	
# of In-center Patients as of the Current Reporting Date	40
# of In-Center Patients as of the Previous Reporting Date	35
Subtract Line 2 from Line 1 (Net In-center Change for 6 Months)	5
Divide Line 3 by Line 2 (6-month Growth Rate)	0.143
Multiply Line 4 by 2 (Annual Growth Rate)	0.286
Multiply Line 5 by Line 1 (New Patients)	11.429
Add Line 6 to Line 1 (Total Patients)	51.429
Divide Line 7 by 2.8 (Total # of Stations Needed)	18.367
# of Stations as of the Current Reporting Date	11.000
Subtract Line 9 from Line 8 (Additional Stations Needed)	7.367

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed at Leland Dialysis is seven, based on rounding allowed in Condition 1.b.(vii). Condition 1a.(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.*” The applicant proposes to add four new stations; therefore, the application is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2020 SMFP applicable to this review. Policy GEN-3: Basic Principles, on page 31 of the 2020 SMFP states:

“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide

these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

Promote Safety and Quality

The applicant describes how it believes the proposed project will promote safety and quality in Section B.5 (a) and (d), pages 13-14 and 15-16, Sections N.1 and N.2(b), page 50; Section O, pages 52-53; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project will promote equitable access in Section B.5 (b) and (d), pages 15-16, Section C.7, page 23; Section L, pages 46-48; Sections N.1 and N.2(c), page 50; 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.5 (c) and (d), pages 15-16; Sections N.1 and N.2(a), page 50; 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 safety and quality, equitable access, and maximum healthcare 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 the facility need methodology as applied from the 2020 SMFP.
 - The applicant adequately demonstrates that the application is consistent with Policy GEN-3 because the proposal demonstrates how it will promote safety and quality, provide equitable access and maximize healthcare value in the provision of dialysis services.
- (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, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to add no more than four dialysis stations to the existing facility pursuant to the facility need methodology for a total of no more than 16 dialysis stations upon project completion.

On page 113, the 2020 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 is Brunswick County. Facilities may serve residents of counties not included in their service area.

The following tables illustrate current and projected patient origin for in-center patients at Leland Dialysis:

Leland Dialysis Historical Patient Origin CY 2019

COUNTY	# IN-CENTER PTS.	% OF TOTAL
Brunswick	25	62.5%
Columbus	6	15.0%
New Hanover	3	7.5%
Bladen	3	7.5%
Georgia	2	5.0%
Other States	1	2.5%
Total	40	100.0%

Source: Application page 19

**Leland Dialysis Projected Patient Origin
 2nd Full Operating Year, CY 2023**

COUNTY	# IN-CENTER PTS.	% OF TOTAL
Brunswick	31	67.4%
Columbus	6	13.0%
New Hanover	3	6.5%
Bladen	3	6.5%
Georgia	2	4.3%
Other States	1	2.3%
Total	46	100.0%

Source: Application page 20

In Section C, pages 20-21 and Section Q, Form C, the applicant provides the assumptions and methodology used to project patient origin. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, page 22, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 22, the applicant references Section B, Question 3 of its application, page 11, wherein it demonstrates that up to 11 additional dialysis stations are needed at Leland Dialysis based on the facility need methodology in the 2020 SMFP. The facility does not offer home hemodialysis or peritoneal dialysis services.

- The applicant states Leland Dialysis was dialyzing 36 in-center patients as of December 31, 2018, which was a utilization rate of 90% based on 10 stations [$36 / 10 = 3.6$; $3.6 / 4 = 0.90$]. Of the 36 in-center patients, the applicant states 27 were residents of Brunswick County.
- As reported in the ESRD Data Collection Form for ESRD facilities submitted to the Agency in February 2020, Leland Dialysis was dialyzing 40 in-center patients as of December 31, 2019, which was a utilization rate of 91% based on 11 stations [$40 / 11 = 3.64$; $3.64 / 4 = 0.91$]. Of the 40 in-center patients, 25 lived in Brunswick County.
- The applicant notes that the Five Year Average Annual Change Rate (AACR) in Brunswick County as reported in Table 9C, page 166 in the 2020 SMFP was 2.1%; however, the applicant averaged the facility's growth over the last two years of operation to be 7.0%, as illustrated in the following table from page 20:

Leland Dialysis Two Year Average Growth Rate, 2017-2019

DATE AND PT. CENSUS		GROWTH RATE	AVERAGE GROWTH RATE
12/31/2017	35		
12/31/2018	36	2.9%	7.00%
12/31/2019	40	11.1%	

The applicant states it is reasonable to assume a 6.0% growth rate for Leland Dialysis, because it is less than the actual experience of the facility.

- The applicant states Leland Dialysis had 12 dialysis stations as of January 1, 2020, when Project ID #O-11678-19 (add no more than one dialysis station) was complete.
- The applicant does not assume any growth in patients from counties outside of Brunswick County.
- Operating Year (OY) 1 is calendar year (CY) 2022, January 1-December 31, 2022 and OY2 is CY 2023, January 1-December 31, 2023.

Projected Utilization

In Section C.3, page 21, the applicant provides a table to illustrate its methodology used to project in-center utilization, as shown below:

	# Stations	Patients
The applicant begins with the Leland Dialysis in-center patients and stations as of December 31, 2019.	11	40
Project Brunswick County patient population forward one year to December 31, 2020 using a 6.0% growth rate.		$25 \times 1.06 = 26.5$
Add 15 patients from outside Brunswick County. This is the ending census as of December 31, 2020.		$26.5 + 15 = 41.5$
Project ID #O-11678 certified on 12/31/2019, increasing stations by one	$11 + 1 = 12$	
Project Brunswick County patient population forward one year to December 31, 2021 using a 6.0% growth rate.		$26.5 \times 1.06 = 28.09$
Add 15 patients from outside Brunswick County. This is the ending census as of December 31, 2021.		$28.09 + 15 = 43.09$
Projected certification date for this project is 1/1/2022. The station count as of this date is 16.	$12 + 4 = 16$	
Project Brunswick County patient population forward one year to December 31, 2022 using a 6.0% growth rate.		$28.09 \times 1.06 = 29.775$
Add 15 patients from outside Brunswick County. This is the ending census as of December 31, 2022.		$29.775 + 15 = 44.775$
Project Brunswick County patient population forward one year to December 31, 2023 using a 6.0% growth rate.		$29.775 \times 1.06 = 31.562$
Add 15 patients from outside Brunswick County. This is the ending census as of December 31, 2023.		$31.562 + 15 = 46.562$

The applicant projects to serve 45 in-center patients in OY 1 and 47 in-center patients in OY 2. Thus, the applicant projects that Leland Dialysis will have a utilization rate of 70.3% or 2.81 patients per station per week [$45 \text{ patients} / 16 \text{ stations} = 2.813$; $2.813 / 4 = 0.703$ or 70.3%] in OY 1. The projected utilization of 2.81 patients per station per week at the end of OY 1 exceeds the minimum standard of 2.8 in-center patients per station per week required by 10A NCAC 14C .2203(b).

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

- The applicant begins the projections with the existing patient census as of December 31, 2019 as reported in the ESRD Data Collection Forms.
- The applicant projects the Brunswick County patient census at Leland Dialysis will increase by 6.0%; less than the 7.0% average growth actually experienced by the facility over two years, but more than the 2.1% Five Year AACR for Brunswick County as reported in Table 9C of the 2020 SMFP.
- The applicant does not project any growth in the number of out-of-county patients in the first two operating years of the project and adds them to the patient census at appropriate points in time.
- The utilization rate by the end of OY 1 exceeds the minimum standard of 2.8 patients per station per week.

Access

In Section C.7, pages 23-24, the applicant states:

“By policy, the proposed services will be made available to all residents in its service area without qualifications. The facility will serve patients without regard to race, sex, age, or handicap. We will serve patients regardless of ethnic or socioeconomic situation.

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.”

In Section L.3, page 47, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project:

**Leland Dialysis
Projected Payor Mix CY 2023**

PAYMENT SOURCE	IN-CTR. DIALYSIS	
	# OF PATIENTS	% OF TOTAL
Self-pay	0.0	0.0%
Insurance*	3.5	7.5%
Medicare*	38.4	82.5%
Medicaid*	2.3	5.0%
Other (VA)	2.3	5.0%
Total	46.5	100.0%

*Including any managed care plans
Totals may not sum due to rounding

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

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

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

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

- (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, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose a reduction, elimination or relocation of a facility or service; therefore, Criterion (3a) is not applicable to this review.

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

CA

The applicant proposes to add no more than four dialysis stations to the existing facility pursuant to the facility need methodology for a total of no more than 16 dialysis stations upon project completion.

In Section E, page 29, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- *Maintain the Status Quo* - The applicant states that maintaining the status quo is not an effective alternative because of the growth rate at the facility.
- *Relocate stations from another DaVita facility* – The applicant states that there are three DaVita facilities in Brunswick County, two of which are operating below 75% of capacity. Southeastern Dialysis Center-Shallotte was operating at 71.43% and relocating stations from that facility would negatively impact patients. Southport Dialysis Center would have less than 10 dialysis stations if four stations were relocated; therefore, this is not an option.

On page 29, the applicant states that the proposal to add four stations to Leland Dialysis pursuant to the facility need determination is the most effective alternative to meet the needs of the dialysis patients served 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
- Information publicly available during the review and used by the Agency

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

1. **Total Renal Care of North Carolina, LLC shall materially comply with all representations made in the certificate of need application.**
 2. **Pursuant to the facility need determination in the 2020 SMFP, Total Renal Care of North Carolina, LLC shall develop no more than four additional in-center dialysis stations at Leland Dialysis for a total of no more than 16 in-center stations upon project completion.**
 3. **Total Renal Care of North Carolina, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to add no more than four dialysis stations to the existing facility pursuant to the facility need methodology for a total of no more than 16 dialysis stations upon project completion.

Capital and Working Capital Costs

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

ITEM	COST
Medical Equipment	\$59,400
Non-Medical Equipment	\$3,004
Furniture	\$5,600
Total	\$68,004

In Section Q, the applicant provides the assumptions used to project the capital cost.

In Section F.3, pages 31-32, the applicant states there will be no start-up or initial operating expenses associated with the proposed project because this is an existing facility that is already operational.

Financial Feasibility

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

Leland Dialysis Projected Revenue and Operating Expenses

	OY 1 CY 2022	OY 2 CY 2023
Total Treatments	6,510.83	6,768.10
Total Gross Revenue (charges)	\$2,151,014	\$2,236,010
Total Net Revenue	\$2,051,399	\$2,132,458
Average Net Revenue per Treatment	\$315.07	\$315.07
Total Operating Expenses (costs)	\$2,048,047	\$2,107,450
Average Operating Expense per Treatment	\$314.56	\$311.38
Net Income	\$3,352	\$25,008

Numbers may not sum due to rounding

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs, and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Availability of Funds

In Section F, page 30, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	DaVita	Total
Loans	\$	\$
Accumulated reserves or OE *	\$68,004	\$68,004
Bonds	\$	\$
Other (Specify)	\$	\$
Total Financing	\$68,004	\$68,004

* OE = Owner's Equity

Exhibit F contains the Consolidated Financial Statements for years ending December 31, 2019 that show DaVita, Inc., parent company to Total Renal Care of North Carolina, LLC currently has \$1.1 billion in cash and cash equivalents and \$17 billion in total assets. Exhibit F.2 provides a March 13, 2020 letter signed by DaVita's Chief Accounting Officer that commits the capital to the project.

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.
 - The applicant adequately demonstrates the availability of sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to add no more than four dialysis stations to the existing facility pursuant to the facility need methodology for a total of no more than 16 dialysis stations upon project completion.

On page 113, the 2020 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-Graham counties and Avery-Mitchell-Yancey counties.*” Thus, the service area for this facility is Brunswick County. Facilities may serve residents of counties not included in their service area.

The 2020 SMFP shows a total of four dialysis centers in Brunswick County, three of which are owned or operated by the applicant, as shown in the following table:

Brunswick County Dialysis Facilities

DIALYSIS FACILITY	CERTIFIED STATIONS 12/31/18	# IN-CENTER PTS.	% UTILIZATION	# PTS. / STATION PER WEEK
FMC Brunswick County (BMA)	10	25	62.50%	2.50
Leland Dialysis	10	36	90.00%	3.60
Southeastern Dialysis Center-Shallotte	14	40	71.43%	2.86
Southport Dialysis Center	11	22	50.00%	2.00
Total	45	123		

Source: 2020 SMFP, Table 9B page 151, application page 35.

In Section G.2, page 35, 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:

“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 for the following reasons:

- There is a facility need determination in the 2020 SMFP for four additional stations at Leland Dialysis. The applicant proposes to add four additional dialysis stations.
- The applicant adequately demonstrates that the four proposed dialysis stations are needed in addition to the existing or approved dialysis stations.

Conclusion

The Agency reviewed the:

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

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

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

C

In Section Q Form H Staffing, the applicant provides a table showing current and projected staffing in full time equivalent (FTE) positions for Leland Dialysis, as summarized below.

Leland Dialysis Current and Projected Staffing

POSITION	CURRENT # FTES AS OF 12/31/19	PROJECTED # FTES	
		OY 1 (CY 2022)	OY 2 (CY 2023)
Administrator	1.00	1.00	1.00
Registered Nurse	2.00	2.00	2.00
Patient Care Technician	5.00	6.00	6.00
Dietician	0.50	0.50	0.50
Social Worker	0.50	0.50	0.50
Administration/Bus. Office	1.00	1.00	1.00
Biomedical Technician	0.50	0.50	0.50
Total	10.50	11.50	11.50

Source: Section Q, Form H

The assumptions and methodology the applicant used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.4 Operating Costs. In Section H, pages 37-38, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. Exhibits H-1, H-2 and H-3 provide supporting documentation. In Section H.4, page 38, the applicant identifies the current medical director for the facility. In Exhibit H-4, the applicant provides a letter from medical director indicating his intent to continue to serve as medical director for the proposed services.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide 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 for the reasons stated 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

In Section I, page 39, the applicant states that the following ancillary and support services are necessary for the proposed services:

Leland Dialysis	
Ancillary and Support Services	
Services	Provider
Self-care training	On site
Home training HH PD Accessible follow-up program	Referral to New Hanover Dialysis Referral to Wilmington Dialysis New Hanover Dialysis for HHD; Wilmington Dialysis for PD
Psychological counseling	On site by RN
Isolation – hepatitis	On site
Nutritional counseling	On site by RD
Social Work services	On site by MSW
Acute dialysis in an acute care setting	Referral to New Hanover Regional Medical Center
Emergency care	Referral to New Hanover Regional Medical Center
Blood bank services	Referral to New Hanover Regional Medical Center
Diagnostic and evaluation services	Referral to New Hanover Regional Medical Center
X-ray services	Referral to New Hanover Regional Medical Center
Laboratory services	DaVita Laboratory Services, Inc.
Pediatric nephrology	Referral to New Hanover Regional Medical Center
Vascular surgery	Referral to New Hanover Regional Medical Center
Transplantation services	Referral to Duke University Medical Center
Vocational rehabilitation & counseling	Vocational Rehab - Wilmington
Transportation	Brunswick Transit

In Section I, pages 39-40, the applicant describes its existing and proposed relationships with other local health care and social service providers. In Exhibit I, the applicant provides supporting documentation for established relationships with local health care providers and for referrals.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

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.

- (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.

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 no more than four dialysis stations to the existing facility pursuant to the facility need methodology for a total of no more than 16 dialysis stations upon project completion.

In Section K, page 42, the applicant states that the project involves no renovation or upfit or new construction. In Section K.3, page 42, the applicant states DaVita typically designs new building with sufficient space to accommodate expansion. Line drawings are provided in Exhibit K-2.

On pages 42-43, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal.

On page 43, 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, and identifies any applicable energy saving features that will be incorporated into the construction plans.

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 handicapped persons, 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 46, the applicant provides the historical payor mix for Leland Dialysis patients during CY 2019 for its existing services, as shown in the table below:

**Leland Dialysis
 Historical Payor Mix CY 2019**

PAYMENT SOURCE	IN-CTR. DIALYSIS	
	# OF PATIENTS	% OF TOTAL
Self-pay	0.0	0.0%
Insurance*	3.0	7.5%
Medicare*	33.0	82.5%
Medicaid*	2.0	5.0%
Other (VA)	2.0	5.0%
Total	40.0	100.0%

*Including any managed care plans
 Totals may not sum due to rounding

In Section L.1(a), page 45, the applicant provides the following comparison:

	PERCENTAGE OF TOTAL PATIENTS SERVED	PERCENTAGE OF THE POPULATION OF THE SERVICE AREA
Female	43.2%	52.2%
Male	56.8%	47.8%
Unknown	0.0%	0.0%
64 and Younger	35.1%	68.5%
65 and Older	64.9%	31.5%
American Indian	0.0%	0.8%
Asian	0.0%	0.8%
Black or African-American	73.0%	10.3%
Native Hawaiian or Pacific Islander	2.7%	0.1%
White or Caucasian	24.3%	82.1%
Other Race	0.0%	1.7%
Declined / Unavailable	0.0%	0.0%

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 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 handicapped persons 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, the applicant states in Section L, page 46, that the facility is not under any obligation to provide uncompensated care, community service, or access by minorities and handicapped persons.

In Section L, page 46, the applicant states that during the last five years 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.

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.3, page 47, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as summarized in the following table.

Leland Dialysis
Projected Payor Mix CY 2023

PAYMENT SOURCE	IN-CTR. DIALYSIS	
	# OF PATIENTS	% OF TOTAL
Self-pay	0.0	0.0%
Insurance*	3.5	7.5%
Medicare*	38.4	82.5%
Medicaid*	2.3	5.0%
Other (VA)	2.3	5.0%
Total	46.5	100.0%

*Including any managed care plans
Totals may not sum due to rounding

As shown in the table above, in the second full year of operation, the applicant projects that no dialysis services will be provided to self-pay patients; 82.5% will be provided to Medicare patients; and 5.0% of services will be provided to Medicaid patients.

On page 47, the applicant provides the assumptions and methodology it uses to project payor mix during the second full year of operation following completion of the project, stating the payor mix is based upon recent facility history of actual treatment volumes.

The projected payor mix is reasonable and adequately supported because the projected payor mix is based on the historical payor mix of 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, pages 47-48, 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

In Section M, page 49, 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-2.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.

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

C

The applicant proposes to add no more than four dialysis stations to the existing facility pursuant to the facility need methodology for a total of no more than 16 dialysis stations upon project completion.

On page 113, the 2020 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-Graham counties and Avery-Mitchell-Yancey counties.”* Thus, the service area for this facility is Brunswick County. Facilities may serve residents of counties not included in their service area.

The 2020 SMFP shows a total of four dialysis centers in Brunswick County, three of which are owned or operated by the applicant, as shown in the following table:

Brunswick County Dialysis Facilities

DIALYSIS FACILITY	CERTIFIED STATIONS 12/31/18	# IN-CENTER PTS.	% UTILIZATION	# PTS. / STATION PER WEEK
FMC Brunswick County (BMA)	10	25	62.50%	2.50
Leland Dialysis	10	36	90.00%	3.60
Southeastern Dialysis Center-Shallotte	14	40	71.43%	2.86
Southport Dialysis Center	11	22	50.00%	2.00
Total	45	123		

Source: 2020 SMFP, Table 9B page 151, application page 35.

Regarding the expected effects of the proposal on competition in the service area, in Section N.1, page 50, 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.

The expansion of Leland 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.”

Regarding the impact of the proposal on cost effectiveness, quality, and access to medically underserved groups, in Section N.2, page 50, the applicant states:

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

Considering all the information in the application, 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 (see Sections C, F, N and Q of the application and any exhibits)
- Quality (see Sections C, N and O of the application and any exhibits)
- Access to medically underserved groups (see Sections C, L and N of the application and any exhibits)

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 based on the reasons stated above.

(19) Repealed effective July 1, 1987.

- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Section Q Form A Facilities, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity.

In Section O.2, pages 52-53, the applicant states that, during the 18 months immediately preceding the submittal of the application, an incident related to quality of care that resulted in a finding of “*Immediate Jeopardy*” occurred in one DaVita facility; Waynesville Dialysis Center. The applicant states that a plan of correction was prepared and accepted, and that Waynesville Dialysis Center is currently back in compliance. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all DaVita 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.
- (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 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- The applicant is not proposing to establish a new kidney disease treatment center or dialysis facility.

- (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.3, page 21, the applicant projects that Leland Dialysis will serve 45 in-center patients on 16 stations, or a rate of 2.81 patients per station per week, as of the end of the first operating year following project completion. This exceeds the minimum performance standard of 2.8 patients per station per week.

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

-C- In Section C, pages 20-22, the applicant provides the assumptions and methodology it used to project in-center patient utilization of the facility.