

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: May 10, 2019

Findings Date: May 10, 2019

Project Analyst: Tanya M. Saporito

Team Leader: Gloria C. Hale

Project ID #: O-11678-19

Facility: Leland Dialysis

FID #: 140237

County: Brunswick

Applicant: Total Renal Care of North Carolina, LLC

Project: Add no more than one dialysis station for a total of no more than 12 stations upon completion of this project and Project ID#O-11593-18 (add one station)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Total Renal Care of North Carolina, LLC (TRC), d/b/a Leland Dialysis proposes to add one dialysis station to the existing facility pursuant to the facility need methodology, for a total of 12 stations upon completion of this project and Project ID #O-11593-18 (add one station).

Need Determination

The 2019 State Medical Facilities Plan (2019 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2019 Semiannual Dialysis Report (SDR), Table D, the county need methodology shows there is a surplus of seven dialysis stations in Brunswick County; thus the applicant cannot apply to add any additional stations based on the county need methodology. However, an applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the individual dialysis center, as

reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%, based on a maximum utilization of four patients per station per week. The applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate reported for Leland Dialysis in Table B of the January 2019 SDR is 3.8 patients per station per week, or 95.0% of capacity (3.8 / 4 patients per station = 0.950). This utilization rate was calculated based on 38 in-center dialysis patients and 10 certified dialysis stations (38 patients / 10 stations = 3.8 patients per station per week).

Application of the facility need methodology indicates additional stations are needed for this facility, as illustrated in the following table:

Leland Dialysis Facility Need Analysis

Required SDR Utilization		80%
Center Utilization Rate as of 6/30/17		95.00%
Certified Stations		10
Pending Stations		1
Total Existing and Pending Stations		11
In-Center Patients as of 6/30/18 (Jan 2019 SDR) (SDR2)		38
In-Center Patients as of 12/31/17 (July 2018 SDR) (SDR1)		35
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	3
	Multiply the difference by 2 for the projected net in-center change	6
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/17	0.1714
(ii)	Divide the result of step (i) by 12	0.0143
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/18 until 12/31/18)	0.0857
(iv)	Multiply the result of step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	41.2571
(v)	Divide the result of step (iv) by 3.2 patients per station	12.8929
	and subtract the number of certified and pending stations to determine the number of stations needed	2

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 two stations. Step (C) of the facility need methodology states, “*The facility may apply to expand to meet the need established ..., up to a maximum of ten stations.*” The applicant proposes to add one new station; therefore, the application is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2019 SMFP which is applicable to this review. *POLICY GEN-3: BASIC PRINCIPLES* on page 31 of the 2019 SMFP is applicable to this review because the facility need methodology is applicable to this review. Policy GEN-3 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.”

The applicant addresses Policy GEN-3 as follows:

Promote Safety and Quality

The applicant describes how it believes the proposed project would promote safety and quality in Section B.4(a), pages 9 - 10, Section N.1, page 49, Section O, page 50 and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project would promote equitable access in Section B.4(b), pages 10 - 11, Section L, pages 43 - 47, Section C.3, page 15, Section N.1, page 49 and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project would maximize healthcare value in Sections B.4(c) and B.4(d), page 11, Section C.3, page 15 and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

The applicant adequately demonstrates how its projected volumes incorporate 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 for the reasons stated above.

- (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

TRC proposes to add one in-center dialysis stations to the existing facility for a total of 12 stations upon completion of this project and Project ID#O-11593-18 (add one station). Leland Dialysis does not offer a home dialysis program.

Patient Origin

On page 369, the 2019 SMFP defines the service area for dialysis stations as “*the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area for this facility is Brunswick County. Facilities may serve residents of counties not included in their service area.

In Section C.8, page 18, the applicant provides the facility’s in-center (IC) patient origin as of June 30, 2018, as shown in the following table:

**Leland Dialysis
Historical Patient Origin as of 6/30/18**

COUNTY OF RESIDENCE	# IC PTS.
Brunswick	28
Bladen	1
Columbus	8
New Hanover	1
Total	38

In Section C.1, page 13, the applicant projects in-center dialysis patients for the first two years of operation (calendar years 2021 and 2022) following project completion, as shown in the following table:

**Leland Dialysis
Projected Patient Origin**

COUNTY OF RESIDENCE	# IC PTS.	
	OY 1	OY 2
Brunswick	30	31
Bladen	1	1
Columbus	8	8
New Hanover	1	1
Total	40	41

The applicant provides the assumptions and methodology for its patient origin projections on page 13. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section B.2, page 7, the applicant provides a table to illustrate that the application is filed pursuant to the facility need methodology in the 2019 SMFP utilizing data from the July 2018 and January 2019 SDRs. The facility need methodology shows a need for two additional stations at Leland Dialysis. The applicant proposes to add one additional dialysis station at Leland Dialysis.

In Section C.1, pages 13 - 17, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, and provides its methodology for projecting utilization, summarized as follows:

- The applicant received a certificate of need on February 4, 2019 to add one station to Leland Dialysis pursuant to the facility need methodology. The applicant states that station was certified on March 10, 2019.
- The applicant states that Leland Dialysis had 38 in-center patients as of June 30, 2018, 28 of whom are residents of Brunswick County and 10 of whom lived in Columbus, New Hanover or Bladen counties.
- The applicant projects growth of the Brunswick County in-center dialysis patient population by applying the Five Year Average Annual Change Rate (AACR) of 2.6% found in Table D on page 60 of the January 2019 SDR.
- The applicant does not project growth for patients residing outside of Brunswick County; rather, those patients are added in at the end of the growth calculations for Brunswick County residents.
- The applicant states Operating Year 1 is Calendar Year (CY) 2021, January 1 through December 31, 2021; and Operating Year 2 is CY 2022, January 1 through December 31, 2022.

The information is reasonable and adequately supported for the following reasons:

- The applicant projects patient growth based on historical patient utilization at Leland Dialysis,
- The applicant projects growth of only the Brunswick County patient population, and adds to that growth patients from outside Brunswick County who dialyze at Leland Dialysis,
- The applicant utilizes the Five Year AACR from the January 2019 SDR to project patient growth,
- The applicant projects utilization based on the needs of the facility's current dialysis patient population.

Projected Utilization

The applicant's methodology, which begins with the Brunswick County in-center patient census as of June 30, 2018 and applies the Brunswick County 2.6% AACR, is illustrated in the following table, from application page 14:

Date	# Patients	Growth Rate	End Patients	+ Out of SA Patients	Total Year End Census
06/30/18	28	1.3%	28.364	10	38.364
01/01/19	28.364	2.6%	29.101	10	39.101
01/01/20	29.101	2.6%	29.858	10	39.858
01/01/21	29.858	2.6%	30.634	10	40.634
01/01/22	30.634	2.6%	31.431	10	41.431

The applicant averages the beginning and ending census for each project year and then rounds mathematically to the nearest whole number. Thus, the applicant projects to serve 40 in-center patients or 3.33 patients per station per week ($40 / 12 = 3.333$) by the end of Operating Year 1, and 41 in-center patients or 3.42 patients per station per week ($41 / 12 = 3.416$) by the end of Operating Year 2 at Leland Dialysis. This satisfies the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

Projected utilization of in-center patients is reasonable and adequately supported for the following reasons:

- The applicant projects the starting patient census for the proposed facility based on existing Leland Dialysis patients.
- The applicant's growth projections are based on an assumption that patient census will increase at an annual rate of 2.6%, which is consistent with the Five Year Average Annual Change Rate (AACR) for Brunswick County, as reported in Table D of the January 2019 SDR.
- The resulting projected utilization rate at Leland Dialysis by the end of the first year is above the minimum standard of 3.2 patients per station per week.

Access

In Section C.3, page 15, the applicant states that, by policy, the proposed services will be available to all patients in need of dialysis, without regard to race, sex, age, handicap, socioeconomic status or the ability to pay. In Section L.1, page 44, the applicant projects the following payor mix during the second full fiscal year of operation (CY 2022) following completion of the project, as illustrated in the following table.

PAYMENT SOURCE	% IN-CENTER PATIENTS
Medicare	27.8%
Medicaid	8.3%
Commercial Insurance	11.1%
Medicare/Commercial	27.8%
Medicare/Medicaid	22.2%
VA	2.8%
Total	100.0%

*Source: Application page 44.

Note: numbers 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 to reduce, eliminate or relocate a facility or a service. The applicant proposes to add four dialysis stations to an existing facility pursuant to the facility need determination. 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

In Section E.1, page 22, the applicant discusses the alternatives considered prior to submitting this application, which include:

1. Maintain the Status Quo – based on the growth rate at Leland Dialysis, the applicant dismissed this option.
2. Relocate existing stations from another DaVita facility in Brunswick County - The applicant states that there are three existing DaVita dialysis facilities in Brunswick County. One facility, Southport Dialysis, was operating at less than 80% capacity. However, the applicant states that Southport Dialysis only operates three days per week in response to the demands of the patients served by that facility and the scheduling needs of the nephrologists.

In Section E.2, page 22, the applicant states the facility need methodology demonstrates a need for the proposed station addition at this facility, and continuing to operate at current capacity without adding an additional station could create a situation in which a third dialysis shift would be necessary, which the applicant states is inconvenient for patients. After considering these alternatives to its proposal, the applicant believes the most effective and least costly alternative is to add one station to ensure adequate access for the patients of Leland Dialysis.

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 the reasons stated above. Therefore, the application is approved subject to the following conditions:

1. **Total Renal Care of North Carolina, LLC d/b/a Leland Dialysis shall materially comply with all representations made in the certificate of need application.**
 2. **Pursuant to the facility need determination in the January 2019 SDR, Total Renal Care of North Carolina, LLC shall develop no more than one additional dialysis station for a total of no more than 12 certified stations at Leland Dialysis upon project completion, which shall include any home hemodialysis training or isolation stations.**
 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 the 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

TRC proposes to add one dialysis station to the existing facility for a total of 12 stations upon completion of this project and Project ID #O-11593-18 (add one station).

Capital and Working Capital Costs

In Section F.1, page 23, the applicant projects the total capital cost of the project as shown in the following table:

ITEM	COST
Dialysis Machines	\$14,850
Other Equipment / Furniture	\$3,620
Total Capital Cost	\$18,470

In Sections F.10 and F.11, pages 25 - 26, the applicant states that Leland Dialysis is an existing facility; therefore, there are no start-up or operating expenses associated with the addition of one dialysis station.

Availability of Funds

In Section F.2, page 24, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

TYPE	LELAND DIALYSIS	TOTAL
Loans	--	--
Accumulated reserves or OE *	\$18,470	\$18,470
Bonds	--	--
Other (Specify)	--	--
Total Financing	\$18,470	\$18,470

* OE = Owner's Equity

Exhibit F-5 contains a letter dated March 13, 2019 from the Chief Accounting Officer for DaVita, authorizing and committing cash reserves of DaVita, Inc. for the capital costs of the project. Exhibit F-7 contains a copy of the balance sheet for DaVita, Inc. for the year ending December 31, 2018. The report indicates that as of December 31, 2018, DaVita, Inc. had \$323,038,000 in cash and cash equivalents, \$19 billion in total assets and \$5 billion in net assets (total assets less total liabilities).

Financial Feasibility

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

	CY 2021 OPERATING YEAR 1	CY 2022 OPERATING YEAR 2
Total Treatments	5,854	6,002
Total Gross Revenues (Charges)	\$2,002,923	\$2,053,010
Total Net Revenue	\$1,926,366	\$1,974,524
Average Net Revenue per Treatment	\$329.07	\$328.97
Total Operating Expenses (Costs)	\$1,808,954	\$1,855,167
Average Operating Expense per Treatment	\$308.80	\$309.09
Net Income	\$ 117,412	\$ 119,357

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section R 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.

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 availability of sufficient funds for the capital needs of the proposal.
 - 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 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

TRC proposes to add one dialysis station to the existing facility for a total of 12 stations upon completion of this project and Project ID# O-11593-18 (add one station).

On page 369, the 2019 SMFP defines the service area for dialysis stations as *“the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.”* Thus, the service area for this facility is Brunswick County. Facilities may serve residents of counties not included in their service area.

The applicant operates three dialysis facilities in Brunswick County. BMA is the only other provider of dialysis services in Brunswick County, and currently operates one dialysis center. The existing and approved Brunswick County dialysis facilities are shown below:

Facility	Provider	# Certified Stations	# Patients	# Patients per Station	% Utilization
FMC Brunswick County	BMA	10	25	2.5	62.50%
Leland Dialysis	TRC	10	38	3.8	95.00%
SEDC-Shallotte	TRC	14	48	4.8	120.00%
Southport Dialysis Center	TRC	11	19	1.7	43.18%
Totals		45	130		

Source: January 2019 SDR, Table B, page 38.

In Section G, page 29, 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:

“One of the three DaVita facilities in Brunswick County was operating at less than 80% utilization as reported in the January [2019] SDR. As discussed in Section E, Southport Dialysis operates on a schedule of three days a week and transferring stations from this facility would negatively impact this facility’s operations. In Section B-2 and Section C of this application, we demonstrate the need that Leland Dialysis has for adding 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."

Southport Dialysis Center operates three days per week to accommodate the existing patients and admitting nephrologists. Given that it is open three days per week instead of six, the utilization at Southport Dialysis Center is actually higher than reported, at 86.36% [19 patients / 11 stations = 1.727 patients per station. $1.727 / 2 = 0.8636$]. The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- The applicant adequately demonstrates that Leland Dialysis needs the additional station proposed in this application.
- Despite the Brunswick County dialysis station surplus reported in the January 2019 SDR, the other DaVita operated dialysis facilities in Brunswick County do not have a sufficient number of stations to be able to relocate stations to the Leland Dialysis facility.
- The apparently low utilization at Southport Dialysis Center is a function of that facility's patients and nephrologists, and is only open three days per week.
- The applicant adequately demonstrates that the proposed station addition is 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 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 H.1, page 30, the applicant provides current and projected staffing for the proposed services. Since the facility is currently operational and the applicant proposes to add only one dialysis station to the existing facility, the applicant proposes to add only one additional Patient Care Technician to the existing staff for the facility. See the following table, from page 30 of the application:

LELAND DIALYSIS CENTER PROJECTED STAFFING CY 2022			
POSITION	CURRENT FTE POSITIONS	FTE POSITIONS TO BE ADDED	TOTAL FTE POSITIONS
Medical Director	NA*	NA*	NA*
Registered Nurse	2.0	0.0	2.0
Patient Care Technician	4.0	1.0	5.0
Administrator	1.0	0.0	1.0
Dietician	0.5	0.0	0.5
Social Worker	0.5	0.0	0.5
Administrative Assistant	1.0	0.0	1.0
Bio-Medical Technician	0.5	0.0	0.5
Total	9.5	1.0	10.5

*Medical Director is an independent contractor, not an employee

The assumptions and methodology used to project staffing are provided in Section R. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, which is found in Section R. In Sections H.3 and H.4, pages 31 - 32, the applicant describes the methods used to recruit or fill new positions and describes its existing training and continuing education programs. In Section I.3, page 35, the applicant identifies the proposed medical director. In Exhibit I-5, the applicant provides a letter from the medical director indicating an interest in continuing 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.1, page 34, the applicant includes a list of providers of the necessary ancillary and support services.

LELAND DIALYSIS ANCILLARY AND SUPPORT SERVICES	
SERVICES	PROVIDER
In-center dialysis/maintenance	Leland Dialysis
Self-care training (in-center)	Leland Dialysis
Home training	
HH PD Accessible follow-up program	SEDC-Wilmington SEDC-Wilmington SEDC-Wilmington
Psychological counseling	Leland Dialysis
Isolation – hepatitis	Leland Dialysis
Nutritional counseling	Leland Dialysis
Social Work services	Leland Dialysis
Acute dialysis in an acute care setting	New Hanover Regional Medical Center
Emergency care	New Hanover Regional Medical Center
Blood bank services	New Hanover Regional Medical Center
Diagnostic and evaluation services	New Hanover Regional Medical Center
X-ray services	New Hanover Regional Medical Center
Laboratory services	DaVita Laboratory Services, Inc.
Pediatric nephrology	New Hanover Regional Medical Center
Vascular surgery	New Hanover Regional Medical Center
Transplantation services	Vidant Medical Center
Vocational rehabilitation & counseling	NC Div of Vocational Rehabilitation Svcs
Transportation	Cape Fear Public Transportation Authority

Source: Application page 34

In Section I.2, page 35, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I-1.

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

Conclusion

The Agency reviewed:

- the application, and
- 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.

NA

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

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

NA

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

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

NA

The applicant does not propose any new construction or renovation of existing space as part of this project. Therefore, Criterion (12) is not applicable to this review.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and 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.7, page 47, the applicant reports that 86.1% of in-center patients who received treatments at Leland Dialysis had some or all of their services paid for by Medicare or Medicaid in CY 2018. The table below shows the historical (CY 2018) payment source for Leland Dialysis:

PAYMENT SOURCE	% PATIENTS
Medicare	27.8%
Medicaid	8.3%
Commercial Insurance	11.1%
Medicare/Commercial Insurance	27.8%
Medicare/Medicaid	22.2%
VA	2.8%
Total	100.0%

Note: numbers may not sum due to rounding.

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant's service area.

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate
Brunswick	31%	52%	18%	14%	13%	15%
Statewide	16%	51%	37%	16%	10%	13%

Source: <http://www.census.gov/quickfacts/table> Latest Data 7/1/17 as of 7/17/18

*Excludes "White alone" who are "not Hispanic or Latino"

**"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2017) refers to the final year of the series (2010 thru 2017). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consisting of North Carolina, South Carolina and Georgia, provides an Annual Report which includes aggregate ESRD patient data from all three states. The 2016 Annual Report does not provide state-specific ESRD patient data, but the aggregate data is likely to be similar to North Carolina's based on the Network's recent annual reports which included state-specific data.

The IPRO SA Network 6 2016 Annual Report (pages 25-26¹) provides the following prevalence data on dialysis patients by age, race, and gender. As of December 31, 2016, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 66% were other than Caucasian and 45% were female.

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 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, in Section L.3, page 46, the applicant states:

“Leland Dialysis has no obligation under any applicable federal regulations to provide uncompensated care, community service or access by minorities and handicapped persons except those obligations which are placed on all medical facilities under Section 504 of the Rehabilitation Act of 1973 and its subsequent amendment in 1993. The facility has no obligation under the Hill Burton Act.”

In Section L.6, page 46, the applicant states, *“There have been no civil rights equal access complaints filed within the last five years.”*

The Agency reviewed the:

- Application
- Exhibits to the application

¹ <https://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/07/NW6-2016-Annual-Report-FINAL.pdf>

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.1(b), page 44, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

**Leland Dialysis Projected Payor Mix
OY 2 (CY 2022)**

PAYMENT SOURCE	% IN-CENTER PATIENTS
Medicare	27.8%
Medicaid	8.3%
Commercial Insurance	11.1%
Medicare/Commercial	27.8%
Medicare/Medicaid	22.2%
VA	2.8%
Total	100.0%

Note: numbers may not sum due to rounding

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 86.1% of total services will be provided to Medicare and Medicaid patients.

On page 44, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

- The applicant projects future payor mix for Leland Dialysis based on the historical sources of payment received by the facility,
- The applicant projects no change in its payor mix following the addition of one station as proposed in this application.

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.4, page 46, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section M, page 48, the applicant states that the Leland Dialysis facility will be offered to nursing students from Brunswick Community College for training purposes and provides supporting documentation in Exhibit M-2.

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

TRC proposes to add one dialysis station to the existing facility for a total of 12 stations upon completion of this project and Project ID #O-11593-18 (add one station).

On page 369, the 2019 SMFP defines the service area for dialysis stations as “*the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area for this facility is Brunswick County. Facilities may serve residents of counties not included in their service area.

The applicant operates three dialysis facilities in Brunswick County. BMA is the only other provider of dialysis services in Brunswick County, and currently operates one dialysis center. The existing and approved Brunswick County dialysis facilities are shown below:

Facility	Provider	# Certified Stations	# Patients	# Patients per Station	% Utilization
FMC Brunswick County	BMA	10	25	2.5	62.50%
Leland Dialysis	TRC	10	38	3.8	95.00%
SEDC-Shalotte	TRC	14	48	4.8	120.00%
Southport Dialysis Center	TRC	11	19	1.7	43.18%
Totals		45	130		

Source: January 2019 SDR, Table B, page 38.

In Section N.1, page 49, the applicant states the expansion of the facility by one station will have no effect on competition in the service area. The applicant discusses how the facility expansion will promote the cost-effectiveness, quality and access to the proposed services. 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 Total Renal Care of North Carolina, LLC.”

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and R of the application and any exhibits)
- Quality services will be provided (see Section O of the application and any exhibits)

- Access will be provided to underserved groups (see Section L of the application and any exhibits)

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.

- (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 A.11, page 5, the applicant states DaVita Inc. owns and operates over 85 dialysis facilities in North Carolina. In Exhibit A-11, the applicant provides a list of those facilities.

In Section O.3, page 50, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in two facilities that are referenced in Exhibit O-3, Southeastern Dialysis Center-Wilmington and Goldsboro South Dialysis. The applicant provides documentation regarding the deficiencies and subsequent measures taken by those facilities to ensure compliance with CMS Conditions for Coverage in Exhibit O-3. After reviewing and considering information provided by the applicant and considering the quality of care provided at all DaVita facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (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 application is conforming to all applicable Criteria and Standards for End-Stage Renal Disease Services. The specific criteria are discussed below.

SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES

10A NCAC 14C .2203 PERFORMANCE STANDARDS

(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.

-NA- The applicant is not proposing to establish a new End Stage Renal Disease facility.

(b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.

-C- In Section C, pages 13 - 14, the applicant demonstrates that Leland Dialysis will serve a total of 40 in-center patients at the end of OY 1 (CY 2021) for a utilization rate of 83.33% or 3.33 patients per station per week (40 patients / 12 stations = 3.333; $3.333 / 4 = 0.833$ or 83.3%). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

-C- In Section C, pages 13 - 14, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.