

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: January 29, 2018

Findings Date: January 29, 2018

Project Analyst: Tanya S. Rupp

Team Leader: Fatimah Wilson

Project ID #: N-11414-17

Facility: Lumbee River Dialysis

FID #: 110715

County: Hoke

Applicant: Total Renal Care of North Carolina, LLC

Project: Add 5 dialysis stations for a total of 15 stations

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

DaVita, Inc. is the parent company of Total Renal Care of North Carolina, LLC (TRC). Total Renal Care of North Carolina, LLC d/b/a Lumbee River Dialysis proposes to add five dialysis stations to its existing facility pursuant to the facility need determination in the 2017 State Medical Facilities Plan (2017 SMFP), for a total of 15 dialysis stations upon project completion.

Need Determination

The 2017 SMFP provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2017 Semiannual Dialysis Report (SDR), the county need methodology shows there is a

surplus of seven dialysis stations in Hoke County. However, the applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80 percent. 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 Lumbee River Dialysis in the July 2017 SDR is 3.5 patients per station per week, or 87.5% (3.5 / 4 patients per station = 0.875). This utilization rate was calculated based on 35 in-center dialysis patients and 10 certified dialysis stations (35 patients / 10 stations = 3.5 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:

OCTOBER 1 REVIEW-JULY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/16		25.0%
Certified Stations		35
Pending Stations		0
Total Existing and Pending Stations		10
In-Center Patients as of 12/31/16 (July 2017 SDR) (SDR2)		35
In-Center Patients as of 6/30/16 (Jan 2017 SDR) (SDR1)		30
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	5
	Multiply the difference by 2 for the projected net in-center change	10
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/16	0.3333
(ii)	Divide the result of Step (i) by 12	0.0278
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/15 until 12/31/16)	0.3333
(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	46.6667
(v)	Divide the result of Step (iv) by 3.2 patients per station	14.5833
	and subtract the number of certified and pending stations to determine the number of stations needed	4.5833

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is five 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 five new stations; therefore, the application is consistent with the facility need determination for dialysis stations.

Policies

Policy GEN-3: Basic Principles on page 33 of the 2017 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.”

Promote Safety and Quality

The applicant describes how it believes the proposed project would promote safety and quality in Section B.4, pages 9 - 11, Section O, page 51, 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, page 10, Section C, page 15, Section L, pages 44 - 47, 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 Section B.4, page 11, Section N, page 50 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 information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- the applicant's use of the facility need methodology in accordance with the July 2017 SDR, and
- the applicant's use of existing policies, historical data, and verifiable sources to provide future projections and demonstrate conformity with Policy GEN-3.

This determination is based on a review of the:

- information in the application, including any exhibits, and
- information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

- (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 five dialysis stations to its existing facility for a total of 15 dialysis stations upon project completion.

Patient Origin

On page 373, the 2017 SMFP defines the service area for dialysis services as the dialysis station 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 consists of Hoke County. Facilities may also serve residents of counties not included in their service area.

In Section C.8, page 18, the applicant identifies the historical patient origin at Lumbee River Dialysis as of December 31, 2016, as shown in the table below:

COUNTY OF RESIDENCE	IN-CENTER PATIENTS
Hoke	9
Robeson	24
Scotland	1
Other States	1
Total	35

In Section C.1, page 13, the applicant identifies the patient population it proposes to serve for the first two years of operation [Operating Year One = OY 1; Operating Year Two = OY 2] following project completion. The applicant proposes to serve only in-center dialysis patients, as illustrated in the following table:

COUNTY	OY 1 CY 2019	OY 2 CY 2020	COUNTY PATIENTS AS % OF TOTAL	
			OY 1	OY 2
Hoke	13	15	26.0%	26.3%
Robeson	35	40	70.0%	70.2%
Scotland	1	1	2.0%	1.8%
Other States	1	1	2.0%	1.8%
Total	50	57	100.0%	100.0%

*Note: CY = Calendar Year

In Section C.1, pages 13 - 15, the applicant provides the assumptions and data utilized to project patient origin.

The applicant adequately identifies the population to be served.

Analysis of Need

In Section C.2, page 15, the applicant states the need for the addition of five stations is provided in Section B.2, which is a table that illustrates the application of the facility need methodology to Lumbee River Dialysis. The discussion regarding the need determination found in Criterion (1) is incorporated herein by reference. See also Section B.2 of the application, on page 15.

Projected Utilization

In Section C.1, page 13, the applicant provides projected patient origin for Lumbee River Dialysis for the first two project years following completion of the project, Calendar Years 2019 and 2020, as shown in the table above.

In Section C.1, pages 13 - 15, the applicant provides the assumptions and methodology used to project in-center utilization, which are summarized below:

- The applicant states the utilization rate for Lumbee River Dialysis as of December 31, 2016 was 87.5%, based on 35 patients dialyzing on 10 in-center stations [35 / 10 = 3.5; 3.5 / 4 = 0.875]. The applicant states that, of the 35 in-center patients who were dialyzing at Lumbee River Dialysis as of December 31, 2016, nine patients were from Hoke County and 26 patients lived in Robeson and Scotland counties and other states.
- The project is scheduled for completion on January 1, 2019, according to the applicant in Section Q, page 54. In Section C.1, page 13, the applicant states OY 1 is CY 2019. OY2 is CY 2020.
- The applicant acknowledges that the Hoke County Five Year Average Annual Change Rate (AACR) found in the July 2017 SDR is 7.0%, and the Robeson County AACR is 4.5%.
- However, based on the actual growth in patient utilization since the facility opened, the applicant chose to use a growth rate that more closely represents the actual facility experience. On page 13, the applicant states:

“...Lumbee River Dialysis experienced an average growth rate of 36.3% ... in the three years since the facility opened. It is therefore reasonable to assume a growth rate of at least 14.0% for the facility, so as to be conservative.”

The applicant provided a table on page 14 to illustrate facility utilization since December 31, 2014, shortly after the facility began serving patients. See the following table, prepared by the analyst:

**Lumbee River Dialysis In-Center Utilization
 12/31/2014 – 12/31/2016**

DATE	# PATIENTS	# STATIONS	% UTILIZATION*	GROWTH RATE
12/31/2014	19	10	47.5%	-
12/31/2015	23	10	57.5%	21.1%
12/31/2016	35	10	87.5%	52.2%
3 Year Average Change Rate				36.3%

*Calculated by (# Patients / # Stations) / 4

Although the applicant did not indicate how it arrived at a growth projection of 14%, that number represents less than one-half of the actual facility growth since 2014. Furthermore, the number represents less than one-half of the one-year net in-center change rate calculated for the facility need methodology (see application Section B.1, page 7). Therefore, it is a reasonable growth rate with which to project utilization at Lumbee River Dialysis through the first two operating years (OYs) following project completion.

In Section C.1, page 14, the applicant provides the calculations it used to project the in-center patient census for OY 1 and OY 2. The applicant separately calculated Robeson

County and Hoke County patient growth, and added the two at the end of each of the two operating years. See the following table, from page 14:

DATE	# SA PATIENTS	X 1.14 = YEAR'S GROWTH	# NON SA PATIENTS	X 1.14 = YEAR'S GROWTH	+ OUT OF SA PATIENTS	TOTAL YEAR END CENSUS
1/1/2017	9	10.26	24	27.36	2	39.62
1/1/2018	10.26	11.69	27.36	31.19	2	44.88
1/1/2019 (OY 1)	11.69	13.33	31.19	35.55	2	50.89
1/1/2020 (OY 2)	13.33	15.20	35.55	40.53	2	57.73

Note: table may not sum due to rounding

The applicant projects to serve 50 in-center patients on 15 stations, which is 3.33 patients per station per week (50 patients / 15 stations = 3.33), by the end of OY 1 and 57 in-center patients on 15 stations, which is 3.8 patients per station per week (57 patients / 15 stations = 3.8), by the end of OY 2. This meets 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 is based on reasonable and adequately supported assumptions regarding continued growth.

Access to Services

In Section L.1, page 44, the applicant states:

“Lumbee River Dialysis, by policy, makes dialysis services available to all residents in its service area without qualifications. WE serve patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability.”

On page 45, the applicant projects that, in the second operating year, 88% of projected patients will have some or all of their services paid for by Medicare or Medicaid The applicant states that the projected payor mix is based on the historical payor mix over the last full operating year. The applicant adequately demonstrates the extent to which all residents, including underserved groups, are likely to have access to the proposed services.

Conclusion

The information in the application, including any exhibits, is based on reasonable and adequately supported assumptions regarding:

- clearly cited, facility-specific historical data from which the applicant identifies the projected patient population and demonstrates the need the projected patient population has for the proposed dialysis services,
- use of established methodologies and assumptions which reasonably demonstrate the need the projected patient population has for the proposed services,

- projected utilization supported by an historical facility growth rate, and
- use of historical facility-specific data to project future access to dialysis services for all residents, including underserved groups.

This determination is based on a review of the:

- information in the application, including any exhibits, and
- information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

- (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 five 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:

- Maintaining the status quo – the applicant dismissed this alternative because of the facility growth rate.
- Relocate stations from another DaVita facility – the applicant states each of the two existing operational DaVita facilities in Hoke County is operating at above 80% utilization; therefore, each facility is eligible for expansion pursuant to the facility need methodology. To relocate existing stations from Dialysis Care of Hoke County would negatively impact the patients at that facility.

After considering the above alternatives, the applicant states that adding five stations to Lumbee River Dialysis proactively addresses the issues of growth and access that are

unique to this facility. Therefore, the proposed project is the most effective alternative to meet the identified need.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- the applicant used reasonable and adequately supported assumptions to project utilization, and
- the data cited by the applicant is reasonable to support the assumptions made with regard to the least costly or most effective alternative for development of the proposed project.

This determination is based on a review of the:

- information in the application, including any exhibits, and
- information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion and is approved subject to the following conditions.

- 1. Total Renal Care of North Carolina, LLC d/b/a Lumbee River Dialysis shall materially comply with all representations made in the certificate of need application.**
 - 2. Pursuant to the facility need determination in the July 2017 SDR, Total Renal Care of North Carolina, LLC shall develop no more than five additional dialysis stations for a total of no more than 15 certified stations at Lumbee River Dialysis upon completion of this project, which shall include any home hemodialysis training or isolation stations.**
 - 3. Total Renal Care of North Carolina, LLC d/b/a Lumbee River Dialysis shall install plumbing and electrical wiring through the walls for no more than five dialysis stations, which shall include any isolation or home hemodialysis stations.**
 - 4. Total Renal Care of North Carolina, LLC d/b/a Lumbee River Dialysis 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 five stations to the existing Lumbee River Dialysis facility for a total of 15 stations upon project completion.

Capital and Working Capital Costs

In Section F.1, page 23, the applicant projects the capital cost for the proposed project will be \$48,464, which includes \$35,750 for dialysis machines and \$12,714 for other equipment and furniture. In Section F.10, pages 25 - 26, the applicant states that there are no projected start-up expenses or initial operating expenses because it is an existing facility that is already operational.

Availability of Funds

In Section F.2, page 24, the applicant states it will finance the capital costs with the accumulated reserves of DaVita. Exhibit F-5 contains a letter dated September 12, 2017, from the Chief Accounting Officer of DaVita, authorizing and committing \$48,464 in capital costs, along with “*any other funds that are necessary for the development of the project*”.

Exhibit F-7 contains the Consolidated Financial Statements for DaVita for the year ending December 31, 2016. These statements indicate that as of December 31, 2016, DaVita had \$913,187,000 in cash and cash equivalents, \$18,741,257,000 in total assets and \$5,822,999,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project.

Financial Feasibility

The applicant provided pro forma financial statements for the first two years of the project. In the pro forma financial statement (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.

	OPERATING YEAR 1	OPERATING YEAR 2
Total Treatments	6,965	7,929
Total Gross Revenues (Charges)	\$2,255,627	\$2,568,212
Total Net Revenue	\$2,194,481	\$2,498,588
Total Operating Expenses (Costs)	\$1,952,593	\$2,164,295
Net Income	\$ 241,888	\$ 334,293

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. 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.

Conclusion

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- the applicant uses reasonable and adequately supported assumptions to project utilization,
- historical data is used to project future costs and charges and demonstrate the project's financial feasibility, and
- the applicant documents sufficient and credible funding for the capital needs of the project.

This determination is based on a review of the:

- information in the application, including any exhibits, and
- information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

- (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 five stations to the existing Lumbee River Dialysis facility for a total of 15 stations upon project completion.

On page 373, the 2017 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 is Hoke County. Facilities may serve residents of counties not included in their service area.

The applicant currently operates two dialysis facilities in Hoke County, and was approved on November 6, 2016 to develop a third facility, East Hoke County Dialysis. The Hoke County dialysis facilities are shown below:

FACILITY	HOKE COUNTY DIALYSIS FACILITIES AS OF DECEMBER 31, 2016				
	# CERTIFIED STATIONS	CON ISSUED, NOT CERTIFIED	# PATIENTS	PATIENTS PER STATION	% UTILIZATION
Lumbee River Dialysis	10	-	35	3.50	87.50%
Dialysis Care of Hoke County	28	-	105	3.75	93.75%
East Hoke County Dialysis	-	10	0	0	0.00%

Source: Table B, July 2017 SDR.

As shown in the table above, both operational facilities in Hoke County were operating at a capacity greater than 80 percent (3.2 patients per station) as of December 31, 2016.

In Section C, pages 13-14, the applicant demonstrates that Lumbee River Dialysis will serve a total of 50 patients at the end of OY 1 for a utilization rate of 83.3%, or 3.33 patients per station per week (50 patients / 15 stations = 3.33; 3.33 / 4 = .833 or 83.3%). The projected utilization of 3.33 patients per station per week for Operating Year One exceeds the 3.2 in-center patients per station threshold as required by 10A NCAC 14C .2203(b). The applicant adequately demonstrates the need to add five additional stations at Lumbee River Dialysis. The discussion on analysis of need found in Criterion (3) is incorporated herein by reference.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- the applicant uses established methodologies and uses assumptions which are reasonable to demonstrate the need for the proposed services, and
- the applicant provides adequate documentation that the proposed services will not result in the unnecessary duplication of existing or approved health service capabilities or facilities.

This determination is based on a review of the:

- information in the application, including any exhibits, and
- information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

- (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 a table to illustrate current staffing. The table shows a total of 9.5 full time equivalent (FTE) positions. The applicant states it will add two Technician positions to the existing facility staff for a total of 11.5 FTE positions following project completion. Otherwise, no new FTE positions will be added, since it is an operational facility.

In Section H.3, pages 31 - 32, the applicant states that it will fill positions by using a DaVita Teammate Recruiter, the Teammate Referral Program, and a Student Internship Program. In addition, the applicant states that it provides a wide range of benefits and competitive salaries to attract qualified candidates for available positions.

In Section H.7, page 33, the applicant provides the projected Direct Care Staff Hours for OY 2. In Section H.2, page 31, the applicant states that the existing medical director for the facility is Dr. John Shepherd, a board certified nephrologist. The applicant states Dr. Shepherd will remain as medical director following the addition of five stations. In Exhibit I-3, the applicant provides a letter signed by Dr. Shepherd, dated August 15, 2017, confirming his commitment to continue to serve as medical director.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- the applicant provides appropriate documentation of the availability of adequate health manpower and management personnel for the provision of the proposed dialysis services,
- the applicant provides appropriate and credible documentation of support from the current and continuing Medical Director at Lumbee River Dialysis, and
- the applicant provides appropriate and credible documentation of the availability of other resources, including methods of recruitment and documentation of staff training, necessary for the provision of the proposed dialysis services.

This determination is based on a review of the:

- information in the application, including any exhibits, and
- information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

- (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 34 - 36, the applicant discusses the provision of necessary ancillary and support services to be provided for the proposed facility, and on page 34, provides a list of service providers. Additionally on page 35, the applicant states that home training services will be provided at Dialysis Care of Moore County.

The applicant provides documentation regarding coordination with the existing health care system in Exhibits I-1 and I-2 including letters from several providers such as Total Renal Laboratories, Inc., Hoke Area Transit Service, Southeastern Regional Medical Center, and FirstHealth Moore Regional Hospital-Hoke, for surgical and pediatric nephrology services. Additionally, the applicant states Duke University Medical Center will provide transplantation services.

The information in the application, including any exhibits, is based on reasonable and adequately supported assumptions regarding:

- agreements for the provision of necessary ancillary services required for the provision of the proposed services,
- agreements for the referral and transfer of dialysis patients for inpatient hospital services and transplant services, and
- identified relationships with the medical community, including physicians and hospitals.

This determination is based on a review of the:

- information in the application, including any exhibits, and
- information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates 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 to:

- construct any new space
- construct more than minimal new space
- renovate any existing space
- make more than minor renovations to existing space

Therefore, Criterion (12) is not applicable to this review.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and 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 48, the applicant provides the payor mix for Lumbee River Dialysis for CY 2016, as shown in the following table:

Lumbee River Dialysis Payor Mix, CY 2016

PAYOR TYPE	% OF TOTAL PATIENTS
Medicare	19.0%
Medicaid	7.1%
Commercial Insurance	9.6%
Medicare/Commercial	33.3%
Medicare/Medicaid	28.6%
VA	2.4%
Total	100.0%

Totals 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**
2016 Estimate	2016 Estimate	2016 Estimate	2016 Estimate	2015 Estimate	2011-2015	2015 Estimate
Hoke	9%	51%	60%	20%	12%	17%
Statewide	16%	51%	37%	16%	10%	13%

Source: <http://www.census.gov/quickfacts/table> Latest Data 7/1/16 as of 8/22/17

*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., V2016) refers to the final year of the series (2010 thru 2016). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consists of North Carolina, South Carolina and Georgia. IPRO SA Network 6 provides a 2015 Annual Report which includes aggregate ESRD patient data from all three states. However, a comparison of the *Southeastern Kidney Council*

*Network 6 Inc. 2014 Annual Report*¹ percentages for North Carolina and the aggregate data for all three states in IPRO SA Network 6 shows very little variance; therefore the statistics for IPRO SA Network 6 are representative of North Carolina.

The IPRO SA Network 6 provides prevalence data on dialysis patients by age, race, and gender in its 2015 annual report, pages 27-28². In 2015, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 67% were non-Caucasian and 45% were female. (IPRO SA Network 6).

The information in the application, including any exhibits, is based on reasonable and adequately supported assumptions regarding:

- the facility's historical payor mix, and
- the extent to which medically underserved populations utilize the applicant's existing services.

This determination is based on a review of the:

- information in the application, including any exhibits, and
- information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that 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 applicants;

C

In Section L.3(d) page 47, the applicant states:

“Lumbee River Dialysis has no obligation under any applicable federal regulation to provide uncompensated care, community service or access by minorities and handicapped persons except those obligations which are placed upon all medical facilities under Section 504 of the Rehabilitation

¹<http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf>

²http://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/05/2015_NW-6_Annual-Report_Final-11-29-2016.pdf

Act of 1973 and its subsequent amendment in 1993. The facility has no obligation under the Hill Burton Act.”

In Section L.6, page 47, the applicant states that there have been no civil rights equal access complaints filed against any DaVita facilities within the last five years.

The information in the application, including any exhibits, is based on reasonable and adequately supported assumptions regarding:

- the facility’s historical payor mix, and
- no existence of any civil rights access complaints against any existing facility owned or operated by the applicant.

This determination is based on a review of the:

- information in the application, including any exhibits, and
- information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates 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, page 67, the applicant projects that 88.0% of the patients who will receive dialysis treatments at Lumbee River Dialysis will have some or all of their services paid for by Medicare or Medicaid. The table below shows the projected OY 2 (CY 2020) payor sources for the facility for in-center patients

Projected Payor Mix, CY 2020

PAYOR TYPE	% OF TOTAL PATIENTS
Medicare	19.0%
Medicaid	7.1%
Commercial Insurance	9.6%
Medicare/Commercial	33.3%
Medicare/Medicaid	28.6%
VA	2.4%
Total	100.0%

Totals may not sum due to rounding

On page 45, the applicant states projected payor mix is based on the historical experience of Lumbee River Dialysis, as shown in Criterion (13a).

The information in the application, including any exhibits, is based on reasonable and adequately supported assumptions regarding:

- the facility's projected payor mix demonstrates adequate access for the medically underserved, and
- the facility's projected payor mix is consistent with the facility's historical payor mix.

This determination is based on a review of the:

- information in the application, including any exhibits, and
- information which was publicly available during the review and used by the Agency

Therefore, the applicant adequately demonstrates 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 47, the applicant describes the range of means by which a person will have access to the dialysis services at Lumbee River Dialysis, including referrals from nephrologists and hospital emergency departments. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to dialysis services.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- Nephrologists may apply to receive medical staff privileges at the facility,
- any Nephrologist may apply to admit patients at the facility, and
- attending physicians may receive referrals from other sources.

This determination is based on a review of the:

- information in the application, including any exhibits, and
- information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates 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.1, page 49, the applicant states that Lumbee River Dialysis has offered the facility as a clinical learning site for nursing students from Sandhills Community College. Exhibit M.2 includes a letter from the applicant to Sandhills Community College dated August 16, 2017, inviting the school to include Lumbee River Dialysis in its clinical rotations for its nursing students.

The information provided in the application, including any exhibits, is based on reasonable and adequately supported assumptions regarding health professional training programs in the area because it shows the applicant offered the facility as a clinical training site for area health professional training programs.

This determination is based on a review of the:

- information in the application, including any exhibits, and
- information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that 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 five stations to the existing Lumbee River Dialysis facility for a total of 15 stations upon project completion.

On page 373, the 2017 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 is Hoke County. Facilities may serve residents of counties not included in their service area.

The applicant currently operates two dialysis facilities in Hoke County, and was approved on November 6, 2016 to develop a third facility, East Hoke County Dialysis. The Hoke County dialysis facilities are shown below:

HOKE COUNTY DIALYSIS FACILITIES AS OF DECEMBER 31, 2016					
FACILITY	# CERTIFIED STATIONS	CON ISSUED, NOT CERTIFIED	# PATIENTS	PATIENTS PER STATION	% UTILIZATION
Lumbee River Dialysis	10	-	35	3.50	87.50%
Dialysis Care of Hoke County	28	-	105	3.75	93.75%
East Hoke County Dialysis	-	10	0	0	0.00%

Source: Table B, July 2017 SDR.

As shown in the table above, both operational facilities in Hoke County were operating at a capacity greater than 80 percent (3.2 patients per station) as of December 31, 2016.

In Section N.1, page 50, the applicant states:

“The expansion of Lumbee River Dialysis will not have an adverse effect on competition in Hoke County. Although the addition of stations that 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 expansion of Lumbee River 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 other [sic] involved in the dialysis process to receive services.”

The information in the application is reasonable and credible and adequately demonstrates that any enhanced competition in the service area includes a positive impact on cost-effectiveness, quality and access to the proposed dialysis services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need for the proposed project and that it is a cost-effective alternative.
- The applicant adequately demonstrates that it will continue to provide quality services.
- The applicant demonstrates that it will continue to provide access to medically underserved populations.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

- (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 Exhibit O-3, the applicant identifies three of its 70+ North Carolina facilities (Lumbee River Dialysis, Southeastern Dialysis Center – Kenansville and Durham Dialysis) as having been cited in the past 18 months for deficiencies in compliance with 42 CFR Part 494, the Centers for Medicare and Medicaid (CMS) Conditions for Coverage of ESRD facilities. The applicant states that all three facilities are back in full compliance with CMS Guidelines as of the date of submission of this application and provides copies of letters to each facility from the Divisions of Health Service Regulation's Acute and Home Care Licensure and Certification Section that confirm each facility is back in compliance. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- the applicant provides adequate and credible documentation of its current policies with regard to providing quality care, and
- the applicant provides accurate information regarding past deficiencies and how those deficiencies were addressed.

This determination is based on a review of the:

- information in the application, including any exhibits, and

- information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that 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.

10 NCAC 14C .2203 PERFORMANCE STANDARDS

.2203(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- Lumbee River Dialysis is an existing facility.

.2203(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.1, pages 13 - 15, the applicant adequately demonstrates that Lumbee River Dialysis will serve at least 50 patients on 15 dialysis stations at the end of the first operating year, which is 3.33 patients per station per week, or a utilization rate of 83.3% ($50 / 15 = 3.33$; $3.33 / 4 = 0.8333$ or 83.33%). The discussion

regarding analysis of need found in Criterion (3) is incorporated herein by reference.

.2203(c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.

-C- In Section C.1, pages 13 - 15, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.