

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

DECISION DATE: January 27, 2012

PROJECT ANALYST: Gebrette Miles
SECTION CHIEF: Craig Smith

PROJECT I.D. NUMBER: N-8725-11 / Total Renal Care of North Carolina, LLC d/b/a Lumbee River Dialysis / Establish a new 10-station dialysis facility in Red Springs by relocating ten stations from Dialysis Care of Hoke County / Hoke County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Department shall review all applications⁰ 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

The applicant, Total Renal Care of North Carolina, LLC d/b/a Lumbee River Dialysis, proposes to establish a new 10 station dialysis facility at 11016 Red Springs Road (NC Highway 211) north of Red Springs by relocating 10 existing stations from its 30-station Dialysis Care of Hoke County facility in Raeford. The proposed site is approximately 8.5 miles from the existing site, three miles from the center of Red Springs, and 9 miles from the center of Raeford. The applicant does not propose to establish new dialysis stations. Therefore, neither the county or facility need methodologies in the *2011 State Medical Facilities Plan* (SMFP) are applicable to this review. However, SMFP Policy ESRD-2 is applicable to this review. Policy ESRD-2 states:

Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties currently served by the facility. Certificate of need applicants proposing to relocate dialysis stations to contiguous counties shall:

1. *demonstrate that the proposal shall not result in a deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*
2. *demonstrate that the proposal shall not result in a surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.*

In summary, the applicant proposes to relocate 10 existing, certified dialysis stations within the host county of Hoke. Consequently, there is no change in the inventory in Hoke County and the application is conforming to Policy ESRD-2 of the 2011 SMFP. Therefore, 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

Total Renal Care of North Carolina, LLC d/b/a Lumbee River Dialysis proposes to establish a new 10 station dialysis facility at 11016 Red Springs Road north of Red Springs by relocating 10 existing stations from its 30-station Dialysis Care of Hoke County facility in Raeford. The proposed site is approximately 8.5 miles from the existing site, three miles from the center of Red Springs, and 9 miles from the center of Raeford. The applicant does not propose to establish new dialysis stations. Additionally, the applicant does not propose any home training. In Section IV.3, the applicant states, "*Dialysis Care of Hoke County has an agreement with DC or Moore County for the provision of home training services.*"

Population to be served

In Section IV.1, page 26, the applicant states that the number of in-center patients served at the Dialysis Care of Hoke County as of December 31, 2010 is as follows:

COUNTY OF RESIDENCE	# OF PATIENTS DIALYZING IN-CENTER
<i>Hoke</i>	72
<i>Robeson</i>	29
<i>Scotland</i>	4
<i>Cumberland</i>	4
<i>Moore</i>	1
<i>Total</i>	110

In Section III.7, page 22, the applicant provided the projected patient origin for Lumbee River Dialysis for the first two years of operation following completion of the project as follows:

COUNTY	OPERATING YEAR 1 2013/4	OPERATING YEAR 2 2014/5	COUNTY PATIENTS AS A PERCENT OF TOTAL	
	IN-CENTER PATIENTS	IN-CENTER PATIENTS	YEAR 1	YEAR 2
Hoke	2	4	6.1%	11.1%
Robeson	29	30	87.8%	83.3%
Scotland	2	2	6.1%	5.6%
TOTAL	33	36	100%	100%

The applicant adequately identified the population it proposes to serve.

Demonstration of Need

In Section III.3(a), page 18, the applicant states:

“Total Renal Care of North Carolina, LLC proposes to relocate ten dialysis stations from Dialysis Care of Hoke County to establish the ten-station Lumbee River Dialysis facility in Hoke County. We feel this will improve the accessibility of services for patients currently traveling from the southern portion of Hoke County and north from Robison [sic] County and Scotland County. The facility will be located at 11016 Red Springs [sic], NC 28377 in Hoke County.”

In Section III.3(b), page 18, the applicant further states:

“Thirty-one patients who get dialysis at the Dialysis Care of Hoke County facility have signed letters of support for the proposed facility. Each of these patients have indicated in their letters that they live closer to the proposed Lumbee River facility and that the facility will be more convenient for them. Based on the fact that teammates from the Dialysis Care of Hoke County facility, including a nurse, patient care technicians, dietician and the social worker will be continuing to be involved in the patients’ care at Lumbee River Dialysis, and because the same DaVita treatment protocols will be used at the new facility, we believe it is reasonable to assume that at least 31 patients now receiving dialysis at Dialysis Care of Hoke County will transfer to the new facility because it is closer to their home.”

Exhibit 15 contains patient letters of support for the proposed project from area nephrologists, as well as 31 patients who are currently dialyzing at the Dialysis Care of Hoke County facility. The patient letters state, in part:

“I fully support a new dialysis facility in Hoke County. Having my dialysis treatments in that part of town would be much more convenient for me. I could travel between that location and my home more easily and quickly, which would

save me time and money. So I would consider transferring to Lumbee River Dialysis for my dialysis treatments. I understand that this statement will in no way require me to transfer, and that decision to transfer is still up to me when the time comes. But I definitely would consider transferring because it would mean a shorter trip to dialysis that would make getting my treatments easier.”

In Section III.3(b), page 18, the applicant states:

“Lumbee River Dialysis is projected to have at least 33 in-center ESRD patients dialyzing in the facility by the end of operating year one for a utilization rate of 3.3 patients per station and 36 in-center patients by the end of operating year 2 for a utilization rate of 3.6 patients per station. The facility is scheduled to be certified on July 1, 2013.”

In Section II.1, pages 11-12, the applicant provides the methodology and assumptions used to project utilization for the first two operating years at the proposed facility. The applicant states:

“Thirty-one patients who currently get dialysis at Dialysis Care of Hoke County have signed letters of support for the proposed Lumbee River Dialysis facility. All of the patients have indicated in their letters that they live closer to the proposed Lumbee River facility and that the facility will be more convenient for them.

Based on these letters, Lumbee River Dialysis will have at least 31 in-center ESRD patients dialyzing in the facility July 1, 2013, which we are projecting to be the beginning of the first year of operation. Those 31 patients are projected to transfer from Dialysis of Hoke County. The facility is projected to have 33 in-center patients by the end of operating year one based on the current Average Annual Change Rate for the Past Five Years that is cited in the July 2011 Semiannual Dialysis Report on the second page of Table B: ESRD Dialysis Station Need Determination by Planning Area. This meets the requirement that at the end of the first operating year the facility shall have at least 32 patients, which documents the need for at least 10 stations.

The July 2011 Semiannual Dialysis Report indicates that the five-year average change rate in Hoke County is 8.8%. Listed below are the calculations that were performed to determine the utilization rates for the proposed Lumbee River Dialysis facility at the end of the first and second operating years:

July 1, 2013-June 30, 2014 is the first operating year.

July 1, 2014-June 30, 2015 is the second operating year.

In-Center Utilization Projections using the average annual change rate for the past five years of 8.8% and starting out with 31 in-center patients dialyzing at Dialysis Care of Hoke County who will transfer their treatments to Lumbee River Dialysis as of July 1, 2013:

July 1, 2013-June 30, 2014 – 31 in-center patients X 1.088 = 33.728

July 1, 2014-June 30, 2015 – 34 in-center patients X 1.088 = 36.696064

Thus, we anticipate that there will be 33 in-center patients dialyzing at the facility at the end of operating year one and 36 in-center patients dialyzing at the facility at the end of year two.” [Emphasis in original.]

As stated above, the applicant used the Hoke County five year average change rate to project utilization for the first and second operation years at the proposed facility. While the proposed facility will be located in Hoke County, the applicant states that the majority of patients will come from Robeson County [29 out of 33 patients (88%) at the end of operating year one and 30 out of 36 (83%) patients at the end of operating year 2.] Thus, the applicant’s methodology of growing the number of patients by the Hoke County five year average change rate of 8.8% may be an overstatement, particularly since the five year average change rate for Robeson County is just 1.9%.

However, there are three Zip codes that straddle the Robeson and Hoke county line: 28357 (Lumber Bridge), 28377 (Red Springs), and 28386 (Shannon). According to the Southeastern Kidney Council (SEKC), the number of in-center dialysis patients in these Zip codes grew by 9% in 2011, as shown in the following table:

**Hemodialysis Patients in
 Robeson/Hoke County Zip Codes**

	1 st Quarter 3/31/2011	2 nd Quarter 6/30/2011	3 rd Quarter 9/30/2011	4 th Quarter 12/31/2011	% Change (3/31/11 to 12/31/11)
28357 (Lumber Bridge)	6	6	6	5	-17%
28377 (Red Springs)	29	28	27	32	10%
28386 (Shannon)	10	12	12	12	20%
Total	45	46	45	49	9%

*Source: 2011 ESRD Prevalence by State/County/ZIPCode Reports

As shown in the table above, Zip codes 28377 (Red Springs) and 28386 (Shannon) grew by 10% and 20%, respectively. These are the Zip codes from which the existing facility currently draws patients. Given the fact that the number of patients in the three Zip Codes that straddle Robeson and Hoke counties grew by 9% last year, the applicant’s use of an 8.8% growth rate in the first two operating years is reasonable and supported. Furthermore, if the 31 patients were projected using only 6% growth per year, the result would be 32 patients and the proposal would conform to the required performance standard of 3.2 patients per station per week, as required 10A NCAC 14C .2203(a).

In Section III.7, page 22, the applicant further states:

“The July 2011 Semiannual Dialysis Report indicates that there were 110 ESRD in-center dialysis patients receiving their treatments at the Dialysis Care of Hoke County, based on data from the SEKC as of December 31, 2010. The facility has 30 certified stations. The facility utilization rate identified in the SDR was 92%.

We are projecting that 31 current in-center patients from the Dialysis Care of Hoke County will transfer to Lumbee River Dialysis.

With 31 patients and ten dialysis stations transferring from the Dialysis Care of Hoke County to Lumbee River Dialysis, this will leave 79 in-center patients and 20 dialysis stations at Dialysis Care of Hoke County if we do not take into consideration any patient growth between January 1, 2011 and when Lumbee River Dialysis is projected to be certified (July 1, 2013).

However, we want to be conservative and project the maximum growth that the population of Dialysis Care of Hoke County will experience because by doing this we will account for all of the potential growth of that population over the entire period from the data presented in the most recent SEKC data report through the point when the station transfer will occur and Lumbee River Dialysis opens. Therefore, even though we have applied the county growth rate to the projected transfer population to Lumbee River Dialysis from January 1, 2011, we have projected the growth of the entire current patient population at Dialysis Care of Hoke County by projecting the growth from the date of the most recent SEKC data, which is December 31, 2010. Taking into consideration that the Dialysis Care of Hoke County had 110 in-center patients as of December 31, 2010 and that Hoke County had an Average Annual Change Rate for the Past Five Years of 8.8%, we have projected the growth in the patient population from January 1, 2011 to the date Lumbee River Dialysis is projected to be certified.

January 1, 2011-December [sic] 31, 2011 – 110 in-center patients X 1.088 = 119.68

January 1, 2012-December [sic] 31, 2012 – 119.68 in-center patients X 1.088 = 130.21184

January 1, 2013-July 31, 2013 – 130.21184 in-center patients X 1.044 = 135.9411609

Using the projections above, Dialysis Care of Hoke County would have 135 in-center patients at the point when Lumbee River Dialysis is projected to be certified on July 1, 2013. With 31 patients and ten dialysis stations transferring from the Dialysis Care of Hoke County to Lumbee River Dialysis, this will leave 104 patients (135 – 31 = 104) and 20 dialysis stations at the Dialysis Care of Hoke County. Once the transfer takes place, using the numbers above, the Dialysis Care of Hoke County utilization rate would be 130%. However, Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Hoke County applied [sic] for an additional seven in-center stations [sic] on September 15, 2011. When the ten stations are transferred to Lumbee River Dialysis, the additional seven stations at Dialysis Care of Hoke County will be certified the same day the ten transferring stations are certified at Lumbee River Dialysis. This will give Dialysis Care of Hoke County 104 in-center patients with 27 dialysis stations for 96% stations utilization, based on the operation of two shifts a day, six days a week. Therefore, based on the available data, and this computation, the needs of

the patients remaining at the Dialysis Care of Hoke County will be adequately met.”

The applicant's projected patient utilization in the first two operating years is reasonable, based on 1) 31 letters from patients at Dialysis Care of Hoke County who have expressed an interest in transferring to the proposed facility; 2) the rate of growth of in-center hemodialysis patients in Hoke County and the three Zip codes shared with Robeson County; and 3) the rate of growth of in-center hemodialysis patients at Dialysis Care of Hoke County. Thus, the application conforms to the required minimum of 3.2 patients per station per week as required by rule 10A NCAC 14C .2203(a).

In summary, the applicant adequately identified the population to be served and demonstrated the need that this population has for a new facility created by relocating 10 existing dialysis stations from Dialysis Care of Hoke County to serve existing patients. Therefore, 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.

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The applicant proposes to relocate 10 existing dialysis stations from Dialysis Care of Hoke County to a new facility, Lumbee River Dialysis, which will be approximately 8.5 miles away. Both facilities will be located in Hoke County.

In Section III.6, page 21, and Section IV.1, page 26, the applicant states that Dialysis Care of Hoke County currently has 110 in-center dialysis patients, 72 of which are from Hoke County. The applicant is projecting that 31 patients from Dialysis Care of Hoke County will transfer to Lumbee River Dialysis.

On page 21, the applicant projects utilization at Dialysis Care of Hoke County, using the Average Annual Change Rate in the July 2011 SDR, through the proposed July 1, 2013 opening of Lumbee River Dialysis, as shown below:

January 1, 2011-December 31, 2011 – 110 in-center patients X 1.088 = 119.68
January 1, 2012-December 31, 2012 – 119.68 in-center patients X 1.088 = 130.21184
January 1, 2013-July 30, 2013 – 130.21184 in-center patients X 1.044 = 135.9411609

Based on these calculations, Dialysis Care of Hoke County is expected to have 104 patients (135 patients – 31 patients transferred = 104) as of July 1, 2013 immediately after the transfer of 31 patients to Lumbee River Dialysis. Thus, the projected utilization at Dialysis Care of Hoke County following the transfer of 10 stations and 31 patients to Lumbee River Dialysis is as follows:

104 patients (after transfer of 31) / 20 stations = 5.2 patients/per station
104 patients / (4 X 20) = 1.3 or 130% utilization

As shown above, the applicant projects a utilization rate of 130% at Dialysis of Hoke County after completion of the proposed project. Regarding this high utilization rate, in Section III.7, page 23, the applicant states:

“However, Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Hoke County applied [sic] for an additional seven in-center stations [sic] on September 15, 2011. When the ten stations are transferred to Lumbee River Dialysis, the additional seven stations at Dialysis Care of Hoke County will be certified the same day the ten transferring stations are certified at Lumbee River Dialysis. This will give Dialysis Care of Hoke County 104 in-center patients with 27 dialysis stations for 96% stations utilization, based on the operation of two shifts a day, six days a week. Therefore, based on the available data, and this computation, the needs of the patients remaining at the Dialysis Care of Hoke County will be adequately met.”

In summary, the patients proposing to transfer to Lumbee River Dialysis have demonstrated their willingness to do so by providing letters of support for the proposed project. The applicant has further demonstrated that the needs of the population presently served at Dialysis Care of Hoke County will continue to be adequately met following the relocation of 10 certified dialysis stations to the proposed facility, as well as the applicant’s planned expansion of the Dialysis Care of Hoke County facility after the completion of the proposed project. See Criterion (13) for discussion of access for the medically underserved. Therefore, the application is conforming to this criterion.

- (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 III.9, pages 23-25, the applicant describes the alternatives considered prior to the submission of its application. The applicant determined that the area in southern Hoke County has more need for a dialysis center than any other area in the county at this time. The application is conforming or conditionally conforming to all other applicable statutory and regulatory review criteria. See Criteria (1), (3), (3a), (5), (6), (7), (8), (12), (13), (14), (18a), (20) and the Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. Consequently, the application is conforming to this criterion 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 its certificate of need application.**

2. **Total Renal Care of North Carolina, LLC d/b/a Lumbee River Dialysis shall develop and operate no more than ten (10) dialysis stations at Lumbee River Dialysis, which shall include any 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 ten (10) dialysis stations which shall include any isolation stations.**
 4. **Total Renal Care of North Carolina, LLC d/b/a Lumbee River Dialysis shall not offer or develop home hemodialysis training services as part of this project.**
 5. **Upon completion of the project, Total Renal Care of North Carolina, LLC shall take the necessary steps to decertify ten (10) stations at Dialysis Care of Hoke County for a total of no more than twenty (20) stations at Dialysis Care of Hoke County.**
 6. **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 Certificate of Need Section 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.

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In Section VIII.1, page 42, the applicant projects that the total capital cost of the project will be \$1,339,574, as shown in the following table:

LUMBEE RIVER DIALYSIS	
Construction Contract	\$ 891,000
Dialysis Machines	\$ 130,250
(RO) Water Treatment Equipment	\$ 90,000
Equipment/Furniture	\$ 111,923
Architect/Engineering Fees	\$ 78,000
Dialysis Chairs	\$ 9,065
Scale	\$ 6,498
Televisions	\$ 22,838
Total	\$1,339,574

In Sections IX.3, page 45, the applicant projects \$136,230 in start-up expenses and \$811,939 in initial operating expenses, for a total working capital of \$948,169 for the first six months of operation. In Section VIII, page 43, the applicant states that Davita, Inc. (parent company of Total Renal Care Inc. and 85% of Total Renal Care of North Carolina, Inc.) will fund this project from cash reserves. Exhibit 20 contains a funding

letter, dated August 11, 2011, from Mr. James K. Hilger, Chief Accounting Officer of DaVita, Inc., which states:

"I am the Vice President and Controller of DaVita, Inc., the parent and 100% owner of Total Renal Care, Inc. I also serve as the Chief Accounting Officer of Total Renal Care, Inc. which owns 85% of the ownership interests in Total Renal Care of North Carolina, LLC ("TRC").

We are submitting a Certificate of Need application to develop a ten-station End Stage Renal Dialysis hemodialysis facility in South Hoke County. The project calls for a capital expenditure of \$1,339,574, start-up expenses of \$136,230 and a working capital requirement of \$811,939.

DaVita and Total Renal Care of North Carolina, LLC have committed cash reserves in the amount of \$2,287,743 for this project. We will ensure that these funds are made available for the development and operation of this project. As Chief Accounting Officer of Total Renal Care of North Carolina, LLC, I can also confirm that we will provide all of the funds that we receive from DaVita for this project to Total Renal Care of North Carolina, LLC for the development of this project."

Exhibit 21 contains the audited financial statements for DaVita, Inc. As of December 31, 2010 DaVita, Inc. had \$860,117,000 in cash and cash equivalents and \$8,114,424,000 in total assets. Therefore, the applicant adequately demonstrated the availability of sufficient funds for the capital and working capital needs of the project.

Based on information provided by the applicant in Section X.1, page 47, the dialysis facility's projected allowable charges per treatment for each payment source are as follows:

SOURCE OF PAYMENT	CHARGE PER TREATMENT
Medicare	\$136.00
Medicaid	\$136.00
Medicare/Medicaid	\$136.00
Commercial Insurance	\$520.00
VA	\$136.00
Medicare/Commercial	\$136.00

The rates shown above are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services. In Sections X.2-X.4, pages 47-49, the applicant reported projected revenues and expenses as follows:

	OPERATING YEAR 1 (7/1/2012 – 6/30/2013)	OPERATING YEAR 2 (7/1/2013 – 6/30/2014)
Total Net Revenue	\$1,667,816	\$1,798,492
Total Operating Costs	\$1,623,877	\$1,731,399
Net Profit	\$43,939	\$67,093

The applicant projects that revenue will exceed operating expenses in each of the first two operating years. The assumptions used in preparation of the pro formas, including the number of projected treatments, are reasonable. See Section X of the application for the applicant's assumptions.

In summary, the applicant adequately demonstrated the availability of sufficient funds for the capital needs, start-up and operating expenses of this project. The applicant also adequately demonstrated that the financial feasibility of the proposal is based on reasonable projections of revenues and operating costs. Therefore, 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.

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The applicant adequately demonstrated the need to establish a new 10-station dialysis facility by relocating 10 stations from Dialysis Care of Hoke County to Lumbee River Dialysis. Dialysis Care of Hoke County is currently the only certified dialysis facility in Hoke County, which is closer to the homes of all 31 patients. According to the most recent Semiannual Dialysis Report (July 2011), Dialysis Care of Hoke County had a utilization rate of 92%. See Criteria (1) and (3) for discussion. Therefore, the applicant adequately demonstrated that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Consequently, 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.

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The following table illustrates projected staffing during the first two operating years following completion of the project, as reported by the applicant in Section VII.1, page 38:

POSITION	# OF FULL TIME EQUIVALENT POSITIONS (FTEs)
RN	1.5
PCT	4.5
Bio-Med Tech	0.3
Med. Dir.	Contracted Position
Admin.	1.0
Dietitian	0.4
Social Worker	0.4
Unit Secretary	1.0
Reuse Tech	0.5
Total	9.6

As shown in the above table, the applicant proposes to employ a total of 9.6 FTE positions to staff the proposed dialysis facility during the first two operating years following completion of the project. In Section V.4, page 30, the applicant states that Dr. John Shepherd will serve as medical director of the facility. Exhibit 14 contains a letter signed by Dr. Shepherd, which states that he has agreed to serve as medical director for the Lumbee River Dialysis facility. In Section VII.2, page 39, the applicant states Dr. Shepherd is Board-Certified in Nephrology.

The applicant has documented the availability of adequate health manpower and management personnel, including the medical director, for the provision of dialysis services. Therefore, 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.

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In Section V.1, page 28, the applicant provides a list of providers of the necessary ancillary and support services. Copies of the agreements with these providers are in: Exhibit 7, letter from First Health regarding a patient transfer agreement with Lumbee River Dialysis; Exhibit 8, letter from Carolinas Medical System regarding an agreement between its transplant center and Lumbee River Dialysis; Exhibit 11, agreement between Dialysis Care of Moore County and Lumbee River Dialysis for home training in home hemodialysis and peritoneal dialysis; and Exhibit 12, copy of a laboratory services agreement executed between DaVita Laboratory Services, Inc., DVA Laboratory Services, Inc., and DaVita, Inc.

The applicant adequately demonstrated that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health system. Therefore, 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

- (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

NA

- (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

- (i) would be available under a contract of at least 5 years duration;
- (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
- (iii) would cost no more than if the services were provided by the HMO; and
- (iv) would be available in a manner which is administratively feasible to the HMO.

NA

- (11) Repealed effective July 1, 1987.

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

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The applicant proposes to construct 7,025 square feet for a construction cost of \$891,000. See Sections VIII and XI.6(h), page 57. The following table illustrates the square footage breakdown as provided by the applicant in Section XI.6(h), page 57:

	ESTIMATED TOTAL SQUARE FEET AFTER NEW CONSTRUCTION RENOVATION OR CONVERSION
Administration Offices Reception & Elev. Lob	521
Public Lobby	383
Mechanical Equipment Mach. Maint, & Freight Elev.	50
Biomedical	100
General Storage/Med Records	487
Exam/Treatment & Med. Offices	264
Staff Lounge and Lockers	360
RO	512
Other (Handicap baths, dock and walkways)	283
Nurses Station	280
Dialysis Stations	2,138
Isolation Room(s)	116
Other (Walkways, Lab, Storage)	95
Miscellaneous	1,436
Total Square Feet	7,025

In Section XI.6(d), page 54, the applicant describes the energy saving features incorporated into the construction plans. The applicant adequately demonstrated that the cost, design and means of construction are reasonable and that the construction costs will not unduly increase the costs and charges of providing the proposed services. See Criterion (5) for discussion of costs and charges. Therefore, the application is conforming to this criterion.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

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In Section VI.1(b), page 33, the applicant reports that 74.4% of the patients who received treatments at Dialysis Care of Hoke County had some or all of their services paid for by Medicare or Medicaid. The table below illustrates the historical payment source of the facility:

DIALYSIS CARE OF HOKE COUNTY	
SOURCE OF PAYMENT	PERCENTAGE
Medicare	20.0%
Medicaid	4.4%
Medicare/Medicaid	23.9%
Commercial Insurance	10.4%
VA	9.8%
Other-Specify: No Ins.	5.4%
Medicare/Commercial	26.1%
Total	100.0%

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages as of June 2010 and CY 2009, respectively. The data in the table were obtained on November 15, 2011. More current data, particularly with regard to the estimated uninsured percentages, were not available.

	Total # of Medicaid Eligible as % of Total Population	Total # of Medicaid Eligibles Age 21 and older as % of Total Population	% Uninsured CY 2008-2009 (Estimate by Cecil G. Sheps Center)
Hoke	19%	6.7%	21.9%
Statewide	17%	6.7%	19.7%

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by Dialysis Care of Hoke County.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage was 48.6% for those age 20 and younger and 31.6% for those age 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. However, as of November 15, 2011, no population data was available by age, race or gender. Even if the data were available, a direct comparison to the applicants' current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women

utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

The applicant demonstrates that medically underserved populations currently have adequate access to the dialysis services provided at Dialysis Care of Hoke County. 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

Lumbee River Dialysis is a new facility and, as such, has no history relevant to uncompensated care, community service, or civil rights access. However, in Section VI.6(a), page 37, the applicant states there have been no civil rights access complaints filed within the last five years in any facilities owned by the parent company in North Carolina.

In Section VI.1(f), page 35, the applicant states:

"Lumbee River Dialysis will have 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 Act of 1973 and its subsequent amendment in 1993. Lumbee River Dialysis will have no obligation under the Hill Burton Act."

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 VI.1(a), page 33, the applicant states:

"Lumbee River Dialysis, by policy, will make dialysis services available to all residents in its service area without qualifications. We will serve patients without regard to race, sex, age, or handicap. We will serve patients regardless of ethnic or socioeconomic situation.

...

Lumbee River Dialysis will not require payment upon admission to its services; therefore, services are available to all patients including low income

persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served persons.”

Exhibit 16 contains DaVita, Inc.’s policies on patient acceptance and admissions. In Section VI.1(c), page 34, the applicant projects that 90.7% of patients will have some or all of their services paid for by Medicare or Medicaid, as illustrated in the following table:

LUMBEE RIVER DIALYSIS	
SOURCE OF PAYMENT	PERCENTAGE
Medicare	25.0%
Medicaid	3.1%
Medicare/Medicaid	31.3%
Commercial Insurance	9.3%
VA	0.0%
Other-Specify: No Ins.	0.0%
Medicare/Commercial	31.3%
Total	100.0%

The applicant demonstrated that it will provide adequate access to the elderly and the medically underserved populations. Therefore, 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 VI.5, page 36, the applicant states that:

“Patients with End Stage Renal Disease will have access to dialysis services upon referral by a Nephrologist with privileges at Lumbee River Dialysis. Lumbee River Dialysis will grant privileges to all qualified nephrologists. Referrals to nephrologists most commonly come from primary care physicians or specialty physicians in Hoke County and other surrounding counties or transfer referrals from other Nephrologists outside of the immediate area. Patients families and friends can obtain access by contacting a Nephrologist with privileges at the facility. Should a patient contact the facility either directly or indirectly, the patient will be referred to a qualified Nephrologist for evaluation and subsequent admission if it were found to be medically necessary. Patients from outside the facility catchment area requesting transfer to this facility will be processed in accordance with the facility transfer and transient policies...The patient, again, will be referred to a qualified Nephrologist for final evaluation and then admission based on the doctor’s orders.”

The applicant adequately demonstrated that it will provide a wide range of means by which a person can access the services. Therefore, 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

Exhibit 13, referenced in Section V.3(c), page 30, contains a letter from Mr. William L. Hyland, the applicant's Director of Healthcare Planning, to the Presidents of Sandhills Community College and Robeson Community College, stating:

"DaVita, Inc., operating as Total Renal Care of North Carolina, Inc. d/b/a Lumbee River Dialysis, is applying to the State of North Carolina for a Certificate of Need to develop and operate a ten-station End Stage Renal Disease dialysis facility to be located in Hoke County. We want to offer to extend our services as a clinical training site for nursing students of the community college once the facility is operational.

We will offer dialysis specific orientation to the nursing students. This will include observation, hands on opportunities in certain areas of treatment, interaction with the dialysis patients and the ability to prepare or initiate Care Plans under the supervision of a nursing instructor from the community college or a registered nurse at the facility."

The information provided in Sections V.3(a)-V.3(c), page 30, and Exhibit 13 is reasonable and credible and supports a finding of conformity with 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

See Sections II, III, V, VI and VII. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the proposal would have a positive impact on cost-effectiveness, quality and access to the proposed services because:

- a) the applicant adequately demonstrated that the proposal is cost effective [See Criteria (1), (3), (4) and (5)];
- b) the applicant demonstrated that it will provide adequate access to the proposed dialysis services [See Criteria (13) for additional discussion];
- c) the applicant adequately demonstrated that it will provide quality services [See Criteria (7), (8) and (20) for additional discussion].

Therefore, 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

The applicant currently provides dialysis services as Dialysis Care of Hoke County facility in Raeford, NC. According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, the facility operated in compliance with the Medicare Conditions of Participation and there were no incidents resulting in a determination of immediate jeopardy during the eighteen months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

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

C

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

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

(a) An applicant that proposes to increase stations in an existing certified facility or relocate stations must provide the following information:

- .2202(a)(1) *Utilization rates;*
-C- See Section IV.1, page 26, and Exhibit 6 (copy of the July 2011 SDR, Tables A and B).
- .2202(a)(2) *Mortality rates;*
-C- In Section IV.2, page 26, the applicant reports the 2008, 2009, and 2010 facility mortality rates.
- .2202(a)(3) *The number of patients that are home trained and the number of patients on home dialysis;*
-C- In Section IV.3, page 26, the applicant states that Dialysis Care of Hoke County has an agreement with DC of Moore County for the provision of home training services. See Exhibit 11 for a copy of the Home Training Agreement.
- .2202(a)(4) *The number of transplants performed or referred;*
-C- In Section IV.4, pages 26-27, the applicant stated that there were no transplants received and 22 patients were referred for transplant evaluation in 2010.
- .2202(a)(5) *The number of patients currently on the transplant waiting list;*
-C- In Section IV.5, page 27, the applicant states that the Dialysis Care of Hoke County has 17 patients on the transplant waiting list.
- .2202(a)(6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*
-C- See Section IV.6, page 27, the applicant reports a total of 94 hospital admissions in 2010; 90.4% were non-dialysis related and 9.6% were dialysis-related.
- .2202(a)(7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during the last calendar year.*
-C- In Section IV.7, page 27, the applicant reports that in 2010 there was one patient with an infectious disease. No patients converted to infectious status in 2010.

(b) *An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:*

- .2202(b)(1) *For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100*
-C- Exhibit 7 contains a letter from the Chief Executive Officer at First Health stating the intent to enter into a Patient Transfer Agreement with the applicant to provide services to patients at the proposed facility.
- .2202(b)(2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*
- (A) *timeframe for initial assessment and evaluation of patients for transplantation,*
 - (B) *composition of the assessment/evaluation team at the transplant center,*
 - (C) *method for periodic re-evaluation,*
 - (D) *criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and,*

- (E) *Signatures of the duly authorized persons representing the facilities and the agency providing the services.*
- C- Exhibit 8 contains a letter of agreement from the Assistant Vice President at Carolinas Medical Center stating the intent to enter into a Transplant Agreement with the applicant to provide services to patients at the proposed facility.
- .2202(b)(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*
- C- In Section XI.6(e) and (f), the applicant states the proposed facility will be supplied with water and power service. Exhibit 9 contains documentation that power will be available at the proposed site.
- .2202(b)(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*
- C- Exhibit 9 contains a copy of written policies and procedures for back up for electrical service in the event of a power outage.
- .2202(b)(5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*
- C- In Section XI, the applicant identifies a primary and secondary site for the proposed facility, which consists of 4.5 acres split into two lots. Exhibit 23 contains a letter from RHGC Investments LLC stating an agreement to be the developer of the proposed project. RHGC Investments LLC will purchase the property and build a shell building that the applicant will up-fit for the proposed facility.
- .2202(b)(6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*
- C- See Sections II.1, page 9; VII.2, page 38 and, XI.6(e), page 55.
- .2202(b)(7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*
- C- See Section III.3, pages 18-19.
- .2202(b)(8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*
- C- In Section III.8, page 23, the applicant states that 100 percent of the anticipated population resides within 30 miles of the proposed facility.
- .2202(b)(9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement for such services.*
- C- In Section II., page 11, the applicant states, "Total Renal Care of North Carolina, LLC d/b/a Lumbee River Dialysis will admit and provide dialysis services to patients who have no insurance or other source of payment, if payment for dialysis services is made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services."

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.

- C- In Section III.3, pages 18-19, the applicant projects to serve 33 in-center patients by the end of the first operating year, for a utilization of 3.3 patients per station, at the proposed facility. See discussion in Criterion (3).
- .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.*
- NA- The applicant is not proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility.
- .2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section II.1, pages 12-13 and Section III.7, pages 22-23, the applicant provides the assumptions and methodology used to project utilization of the proposed facility.

10 NCAC 14C .2204 SCOPE OF SERVICES

To be approved, the applicant must demonstrate that the following services will be available:

- .2204(1) *Diagnostic and evaluation services;*
 - C- See Section V.1, page 28 and Exhibit 7.
- .2204(2) *Maintenance dialysis;*
 - C- See Section V.1, page 28.
- .2204(3) *Accessible self-care training;*
 - C- See Section V.1, page 28.
- .2204(4) *Accessible follow-up program for support of patients dialyzing at home;*
 - C- See Section V.1, page 28 and V.1(d), page 29.
- .2204(5) *X-ray services;*
 - C- See Section V.1, page 28.
- .2204(6) *Laboratory services;*
 - C- See Section V.1, page 28 and Exhibit 12.
- .2204(7) *Blood bank services;*
 - C- See Section V.1, page 28 and Exhibit 7.
- .2204(8) *Emergency care;*
 - C- See Section V.1, page 28, and Exhibit 7.
- .2204(9) *Acute dialysis in an acute care setting;*
 - C- See Section V.1, page 28, and Exhibit 7.
- .2204(10) *Vascular surgery for dialysis treatment patients*
 - C- See Section V.1, page 28, and Exhibit 7.
- .2204(11) *Transplantation services;*
 - C- See Section V.1, page 28, and Exhibit 8.
- .2204(12) *Vocational rehabilitation counseling and services; and,*
 - C- See Section V.1, page 28.
- .2204(13) *Transportation*
 - C- See Section V.1, page 28.

10 NCAC 14C .2205 STAFFING AND STAFF TRAINING

- .2205(a) *To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R. Section 405.2100.*
- C- In Section VII.1, page 38, the applicant provides the proposed staffing. In Section VII.2, page 38, the applicant states the proposed facility will comply with all staffing requirements set forth in 42 C.F.R. Section 405.2100. The applicant adequately demonstrates that sufficient staff is proposed for the level of dialysis services to be provided. See Criterion (7) for discussion.
- .2205(b) *To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.*
- C- See Section VII.5, page 40, and Exhibit 19.

