

## ATTACHMENT – REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA – Conditional

NC – Nonconforming

NA = Not Applicable

Decision Date: February 25, 2015

Findings Date: February 25, 2015

Project Analyst: Tanya S. Rupp

Team Leader: Lisa Pittman

Project ID #: N-10345-14

Facility: Dialysis Care of Hoke County

FID #: 945165

County: Hoke

Applicant(s): Total Renal Care of North Carolina, LLC

Project: Relocate one existing dialysis station from Dialysis Care of Richmond County, for a facility total of 28 dialysis stations upon project completion

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 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.

NC

Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Hoke County is currently certified for 27 in-center dialysis stations. In this application, the applicant proposes to add one dialysis station by relocating one station from Dialysis Care of Richmond County (DC Richmond County), for a total of 28 dialysis stations at Dialysis Care of Hoke County upon completion of this project.

#### **Need Determination**

The 2014 State Medical Facilities Plan (2014 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2014 Semiannual Dialysis Report (SDR), the county need

methodology shows there is no need for an additional dialysis facility or for any additional dialysis stations in Hoke County. According to the facility need methodology, an applicant for dialysis stations is eligible to apply for additional dialysis stations if the utilization rate for the dialysis facility, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. In this application, Dialysis Care of Hoke County (DC Hoke County) is not eligible to apply for additional stations in its existing facility based on the facility need methodology, because the adjusted utilization rate was 2.9 patients per station, or 74%. This utilization rate was calculated based on 110 in-center dialysis patients and 37 certified and pending dialysis stations as of December 31, 2013 (110 patients / 37 stations = 2.9 patients per station).<sup>1</sup> See the following table:

**OCTOBER 1 REVIEW-JULY SDR**

Required SDR Utilization		80%
Center Utilization Rate as of 12/31/13		91.7%
Certified Stations		30
Pending Stations		7
<b>Total Existing and Pending Stations</b>		<b>37</b>
In-Center Patients as of 12/31/13 (SDR2)		110
In-Center Patients as of 6/30/13(SDR1)		110
Step	Description	
(i)	Difference (SDR2 - SDR1)	0
	Multiply the difference by 2 for the projected net in-center change	0
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/14	0.0000
(ii)	Divide the result of Step (i) by 12	0.0000
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/13 until 12/31/14)	0.0000
(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	110.0000
(v)	Divide the result of Step (iv) by 3.2 patients per station	34.3750
	and subtract the number of certified and pending stations as recorded in SDR2 to determine the number of stations needed	-2.6250

Therefore, neither the county or facility need methodology in the 2014 SMFP is applicable to this review.

**Policies**

<sup>1</sup> On February 27, 2012, a certificate of need was issued to Dialysis Care of Hoke County (Project ID #N-8744-11) to add 7 dialysis stations to the existing facility. As of December 31, 2013, that addition was pending, as was the relocation of 10 dialysis stations to the new Lumbee River Dialysis facility (Project ID #N-8725-14).

Policy GEN-3, on page 38 of the 2014 SMFP is not applicable to this review, because the applicant is not proposing to develop a facility pursuant to a need determination in the 2014 SMFP. Policy GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES is likewise not applicable to this review, because the applicant is not proposing a capital expenditure greater than \$2 million.

However, Policy ESRD-2: RELOCATION OF DIALYSIS STATIONS, on page 32 of the 2014 SMFP, is applicable to this review, because the applicant proposes to relocate one dialysis station from DC Richmond County to DC Hoke County. The policy 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 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.”*

DC Hoke County proposes in this application to relocate one existing dialysis station from DC Richmond County, for a total of 28 stations at DC Hoke County and 29 stations at DC Richmond County following completion of this project. Richmond County and Hoke County are contiguous; however, DC Richmond County, the county that will contribute dialysis stations to Hoke County, does not currently serve any patients from Hoke County. The policy states that relocations of existing stations are allowed *“within the host county and to contiguous counties currently served by the facility.”* [emphasis added].

In Section III.7, page 25, the applicant provides projected patient origin for DC Hoke County which is based on its current patient origin:

COUNTY	OY 1 2016	OY 2 2017	COUNTY PATIENTS AS % OF TOTAL	
	IN-CTR.	IN-CTR.	OY 1	OY 2
Hoke	80	85	86.6%	87.6%
Cumberland	2	2	2.2%	2.1%
Moore	1	1	1.1%	1.0%
Robeson	9	9	9.8%	9.3%
Total	92	97	100.0%	100.0%

In addition, in Section III.3, page 22, the applicant states:

*“DC of Hoke County is not eligible to apply for additional dialysis stations since the facility utilization rate was less than 80% based on the 37 dialysis stations in Hoke County. Since Hoke County has a two-station deficit of stations and Richmond County, which is contiguous to Hoke County, has a two-station surplus of stations, it is reasonable to transfer an excess station from Richmond County to Hoke County.”*

However, the applicant did not provide any patient origin data for DC Richmond County. The analyst examined the Data Collection Forms submitted to the Division of Health Service Regulation Medical Facilities Planning Section by the applicant for the four reporting periods since December 31, 2012 [December 31, 2012, June 30, 2013, December 31, 2013 and June 30, 2014]. The form collects information about the facility, including patient census. According to each of the reports reviewed by the analyst, Dialysis Care of Richmond County has not served any patients from Hoke County. See the following table, prepared by the analyst that shows patient origin for DC Richmond County as reported in the June 2014 Data Collection Form:

**DC Richmond County  
Patient Origin as of June 30, 2014**

COUNTY	# IN-CTR. PTS.	# HOME PD PTS.
Anson	1	1
Richmond	88	6
Scotland	6	1
South Carolina	3	1

Moreover, the applicant did not provide support letters from any patients receiving dialysis services in Richmond County who were considering relocating their care to Hoke County. No information provided by the applicant or publicly available shows that any Hoke County patients are served at DC Richmond County. Therefore, since DC Richmond County is the facility that is proposed to lose stations to DC Hoke County, the proposed station relocation is not to a county *“currently served by the facility.”* Therefore, the application is not consistent with Policy ESRD-2.

In summary, the application is not consistent with Policy ESRD-2 in the 2014 SMFP; therefore, the application is not 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.

DC Hoke County proposes to relocate one dialysis station from DC Richmond County to DC Hoke County, for a facility total of 28 stations at DC Hoke County upon project completion. The July 2014 SDR indicates that, as of December 31, 2013, DC Hoke County had 27 certified dialysis stations and DC Richmond County had 30 certified dialysis stations.

**Population to be Served**

In Section III.7, page 25, the applicant identifies the patient population to be served at DC Hoke County during the first two years of operation following project completion, as illustrated in the following table:

COUNTY	OPERATING YEAR 1	OPERATING YEAR 2	PATIENTS AS % OF TOTAL	
			OPERATING YEAR 1	OPERATING YEAR 2
Hoke	80	85	86.9%	87.6%
Cumberland	2	2	2.2%	2.1%
Moore	1	1	1.1%	1.0%
Robeson	9	9	9.8%	9.3%
Total	92	97	100.0%	100.0%

In Section II, pages 15 - 17, and in Section III.7, pages 25 - 26, the applicant provides the assumptions and methodology it uses to project the proposed in-center patient utilization of DC Hoke County following the addition of one dialysis station.

The applicant adequately identifies the population it proposes to serve.

**Demonstration of Need**

In Section III.3, page 22, the applicant states:

*“Hoke County had a projected two-station deficit of dialysis stations as of December 31, 2013. Hoke County has experienced a five year average annual change rate of 12.6% DC of Hoke County has capacity for one additional in-center dialysis station. The county has experienced a significant growth of the ESRD patient population over the years.*

In Section II.1, page 15, and Section III.7, page 26, the applicant states:

*“We are applying for a one-station expansion via transfer of one station from the Dialysis Care of Richmond County in Richmond County. The July 2014 SDR indicates that the five year average annual change rate for Hoke County was 12.6% However, for the purpose of this CON application the growth rate of 6.3% has been used to be conservative. The Lumbee River Dialysis CON application indicated that 31 in-center patients would transfer their care from*

*DC of Hoke County during the first year of operation. Therefore, for the purpose of this CON application thirty-one in-center patients living in Hoke County have been subtracted from the total of 98 Hoke County patients since the Lumbee River Dialysis has been certified  $98 - 31 = 67$  Hoke County patients."*

In Section II.1, page 17, and Section III.7, page 26, the applicant projects utilization for the 28 in-center stations at DC Hoke County following project completion. However, the applicant's calculations are based on 68 patients, not 67. Therefore, the project analyst recalculated the projections based on 67 Hoke County patients. The use of 68 rather than 67 is not fatal to the application. See the following calculations by the project analyst:

- 98 Hoke County patients as of 12/31/13 minus 31 to transfer to Lumbee River Dialysis = 67 remaining Hoke County patients. Hoke County patients are increased at 6.3% per year. No growth is calculated for the patients outside of Hoke County.

The applicant states on page 26 that Project Year One is projected to be January 1, 2016 – December 31, 2016; and Project Year Two is January 1, 2017 – December 31, 2017. Therefore, the following calculations illustrate the projected population for both Project Years:

- 67 Hoke County patients  $\times 1.063 = 71.22$  patients as of December 31, 2014
- 71.22 Hoke County patients  $\times 1.063 = 75.7$  patients as of December 31, 2015
- 75.7 Hoke County patients  $\times 1.063 = 80.5$  patients as of December 31, 2016
- 80.5 Hoke County patients  $\times 1.063 = 85.5$  patients as of December 31, 2017
  
- Project Year One: 80.5 Hoke County patients + 12 out of county = 92.5 in center patients; 92 patients / 28 stations = 3.3 patients per station, or 82% utilization.
- Project Year Two: 85.5 Hoke County patients + 12 out of county = 97.5 in center patients; 97 patients / 28 stations = 3.5 patients per station; or 87% utilization.

The applicant does not project to serve home trained patients at the DC Hoke County facility. Projected utilization of the proposed 28 in-center dialysis stations at DC Hoke County is based on reasonable, credible and adequately supported assumptions.

### **Access to Services**

In Section VI, page 35, the applicant states,

*"DC of Hoke County, by policy, has always made dialysis services available to all residents in its service area without qualifications. We have served and will continue to serve without regard to race, sex, age, handicap, or ethnic and socioeconomic groups of patients in need of dialysis regardless of their ability to pay." [sic]*

In Section VI.1(c), page 36, the applicant projects that 87.9% of its patients will be covered by Medicare or Medicaid; and 2.8% by VA. The applicant adequately demonstrates 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.

## Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need that population has for the addition of one dialysis station at DC Hoke County, and the extent to which all residents of the area, including underserved groups, are likely to have access to the dialysis services proposed. 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.

## C

The applicant proposes to relocate one existing station from DC Richmond County in Richmond County to DC Hoke County in Hoke County, for a total of 29 stations at DC Richmond County and 28 stations at DC Hoke County.

### DC Richmond County

DC Richmond County is currently certified for 30 dialysis stations and, upon completion of this project in which it will lose a station, the facility will have 29 stations.

In Section III.6, page 24, the applicant states:

*“The July 2014 SDR indicated that the Dialysis Care of Richmond County was treating 93 in-center patients as of December 31, 2013. The facility had 27 certified stations and three stations pending certification. The three-station expansion is scheduled to be certified on January 1, 2015. With the transfer of one station to DC of Hoke County on January 1, 2016, this will leave DC of Richmond County with 29 certified stations. This certificate of need application does not call for the transfer of any patients from DC of Richmond County to DC of Hoke County.*

*The July 2014 SDR indicated that Richmond County had a five year average annual change rate of 3.5% as indicated in Table B. The following are growth calculations for the DC of Richmond County for the period January 1, 2014 through December 31, 2017, the proposed end of operating year two for the DC of Hoke County expansion.*

*January 1, 2014 - December 31, 2014 – 93 patients X 1.035 = 96.255*

*January 1, 2015 – December 31, 2015 – 96.255 patients X 1.035 = 99.623925*



*January 1, 2016 – December 31, 2016 – 99.623925 patients X 1.035 = 103.1107623  
January 1, 2017 – December 31, 2016 – 103.1107623 patients X 1.035 =  
106.7196389*

*Based on the information above, the Dialysis Care of Richmond County would have 103 in-center patients at the end of operating year one for a utilization rate of 88.8% or 3.55 patients per station and 106 in-center patients at the end of operating year two for a utilization rate of 91.4% or 3.66 patients per station. The patients at DC of Richmond County will have an adequate number of stations available. If DC of Richmond County experiences a more aggressive growth, Total Renal Care of North Carolina will submit a certificate of need application to increase the number of stations utilizing the facility need methodology.”*

The applicant adequately demonstrates that the needs of the population presently served at DC Richmond County will continue to be adequately met following the proposed relocation of one station to DC Hoke County. 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.

NC

In Section III.9, page 27, the applicant states:

*“There were only two alternatives of meeting the needs of the proposed project considered. [sic] The first was to do nothing. This alternative was dismissed since the patient population continues to grow and there is a two station deficit of stations in Hoke County. The second was to apply for a [one-]station expansion via the transfer of a station from a facility located in a contiguous county. We chose the second alternative in order to help meet the growing demand for dialysis services at DC Hoke County and to eliminate a portion of the station deficit in Hoke County.”*

The applicant concludes that the proposed project would provide a more efficient alternative to serve dialysis patients in Hoke County.

However, the application is not conforming to all other statutory and regulatory review criteria, and thus, is not approvable. The application is not conforming to Criterion (1) or Criterion (14). A project that cannot be approved cannot be an effective alternative. Therefore, the application is not conforming to this criterion.

- (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

In Section VIII.1, page 45, the applicant states that the total capital cost of the project will be \$17,398 which includes \$12,500 for dialysis machines, \$1,185 for water treatment equipment, \$1,135 for dialysis chairs, \$1,500 for televisions, and \$1,078 for a patient computer system.

In Section IX.3, page 49, the applicant projects no working capital (start-up and initial operating expenses) associated with the proposed project, since the facility is currently operational and the application is for the addition of one station.

In Section VIII.2, page 46, the applicant states that the project will be funded from cash reserves; and on page 47, the applicant states DaVita Healthcare Partners Inc., the parent company of DVA Healthcare Renal Care, Inc., will provide the cash reserves.

In Exhibit 18, the applicant provides a September 10, 2014 letter from the Chief Accounting Officer of DaVita Healthcare Partners, which states in part:

*“I am the Chief Accounting Officer of DaVita HealthCare Partners, Inc., the parent and 100% owner of Total Renal Care, Inc. ...*

*We are submitting a Certificate of Need application to expand our Dialysis Care of Hoke County by one ESRD dialysis station. The project calls for a capital expenditure of \$17,398. This letter will confirm that DaVita HealthCare Partners Inc. has committed cash reserves in the total sum of \$17,398 for the project capital expenditure. DaVita HealthCare Partners Inc. will make these funds, along with any other funds that are necessary for the development of the project, available to Total Renal Care of North Carolina.”*

In Exhibit 19, the applicant provides the audited financial statements for DaVita Healthcare Partners, Inc. for the fiscal year ended December 31, 2013. As of December 31, 2013, DaVita Healthcare Partners, Inc. had \$946,249,000 in cash and cash equivalents, \$17,098,877,000 in total assets and \$4,605,541,000 in total equity. The applicant adequately demonstrates the availability of funds for the capital and working capital needs of the project.

In Section X.1, page 51, the applicant provides the allowable charges per treatment for each payment source for DC Hoke County, as illustrated below in the table.

DC HOKE COUNTY	
PAYOR	CHARGE/TREATMENT
Medicare	\$239.02
Medicaid	\$143.00
Medicare/Medicaid	\$239.02
Commercial Insurance	\$1,275.00
VA	\$193.00
Medicare/Commercial	\$239.02

The applicant projects revenues in Section X.2, page 52 and operating expenses in Section X.4, pages 55 - 56 of the application. In Section X.2 - X.4, pages 53-57, the applicant reports projected revenues and expenses for DC Hoke County, as illustrated in the following table:

<b>DC HOKE COUNTY</b>		
	<b>OPERATING YEAR 1</b>	<b>OPERATING YEAR 2</b>
Total Net Revenue	\$4,121,152	\$4,329,103
Total Operating Costs	\$3,436,610	\$3,583,229
<b>Net Profit</b>	<b>\$ 684,542</b>	<b>\$ 745,875</b>

The applicant projects that revenues will exceed operating expenses in each of the two operating years following project completion. The assumptions used in preparation of the proformas, including the number of projected treatments are reasonable, credible and adequately supported. In Section VII.1, page 40 and Section X.5, page 56, the applicant provides projected staffing and salaries. The applicant provides adequate staffing to provide dialysis treatments for the number of patients projected. See Section X of the application for the applicant's assumptions.

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of this project. The applicant also adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of costs and charges. 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.

C

Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Hoke County proposes to relocate one station from DC Richmond County, Richmond County, to DC Hoke County, Hoke County. Total Renal Care of North Carolina, LLC is the only provider of ESRD services in both Richmond and Hoke counties. Total Renal Care of North Carolina, LLC has two facilities in Richmond County, and one existing facility and one facility that was developed but not certified at the time this application was submitted in Hoke County.

The following table identifies the existing dialysis facilities located in Hoke and Richmond Counties, as reported in the July 2014 SDR:

<b>Facility</b>	<b>Location</b>	<b>Utilization</b>
Hoke County		
Dialysis Care of Hoke County	Raeford	91.67%
Lumbee River Dialysis	Raeford	0.00% *
Richmond County		
Dialysis Care of Richmond County	Hamlet	86.11%
Sandhills Dialysis	Rockingham	62.50%

\*This facility is not yet developed

The applicant adequately demonstrates the need to add one station to DC Hoke County based on the projected number of in-center patients to be served and the projected growth in the dialysis patient population in Hoke County. However, the applicant does not adequately demonstrate that this application is consistent with Policy ESRD-2 in the 2014 SMFP. The discussion regarding compliance with Policy ESRD-2 found in Criterion (1) is incorporated herein by reference.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved certified dialysis stations in Hoke County. 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.

C

In Section VII.1, page 40, the applicant provides projected staffing for DC Hoke County following the addition of the one station, as illustrated in the following table:

<b>DC HOKE COUNTY FTE POSITIONS</b>	
RN	4.0
PCT	11.0
Bio-Med Tech	0.5
Admin.	1.0
Dietician	1.0
Social Worker	1.0
Unit Secretary	1.0
Reuse	1.0
<b>Total FTEs</b>	<b>20.5</b>

The applicant states compliance with all staffing requirements in 42 C.F.R. Section 494 (formerly 405.2100). Staffing by shift is provided in Section VII.10 on page 43.

DC Hoke County is an existing facility and is currently fully staffed. The applicant proposes to add one dialysis station with this application, and does not propose additional staff. In Section V.4, page 33, the applicant identifies the Medical Director for DC Hoke County as Dr. John Shepherd. In Exhibit 13 the applicant provides a September 8, 2014 letter from Dr. Shepherd indicating the doctor's support for the project.

The applicant adequately documents the availability of resources, including health manpower and management personnel, for provision of the proposed 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.

C

In Sections V.1 and V.2, pages 31 - 32, the applicant lists the providers of the necessary ancillary and support services that will serve the patients dialyzing at DC Hoke County. FirstHealth Moore Regional Hospital provides emergency services, acute hemodialysis services, diagnostic and evaluation services, X-ray services, blood bank services, and vascular surgery services. The other services are provided by the individual providers listed in the table provided on page 31. In addition, the applicant provides supporting documentation regarding ancillary services in Exhibits 10 and 11. The applicant discusses coordination with the existing health care system in Sections V.2 – V.6, pages 32 - 34. The applicant provides supporting documentation of coordination with the existing health care system in Exhibits 12 and 13. The information provided in those sections and exhibits is reasonable and credible and supports a finding of conformity with 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 (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.

NA

(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 VI.1, page 35, the applicant states

*“DC of Hoke County, by policy, has always made dialysis services available to all residents in its service area without qualifications. We have served and will continue to serve without regard to race, sex, age, handicap, or ethnic and socioeconomic groups of patients in need of dialysis regardless of their ability to pay.”*

The applicant’s dialysis policies, procedures, and guidelines with regard to accepting patients for dialysis care are located in Exhibit 14.

In Section VI.1, page 35, the applicant reports that 87.9% of the patients who received treatments at DC Hoke County had some or all of the services paid for by Medicare or Medicaid in the past year, as shown in the table below:

DC HOKE COUNTY HISTORICAL PAYOR MIX	
PAYOR SOURCE	PERCENTAGE
Medicare	36.1%
Medicaid	4.6%
Medicare/Medicaid	24.1%
Commercial Insurance	9.3%
VA	2.8%
Medicare/Commercial	23.1%
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 for Hoke County and statewide.

	<b>2010 Total # of Medicaid Eligibles as % of Total Population *</b>	<b>2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *</b>	<b>2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *</b>
Hoke County	19%	7%	22%
Statewide	17%	7%	20%

\*More current data, particularly with regard to the estimated uninsured percentages, was not available.

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 dialysis services offered by DC Hoke County. In fact, in 2011 only 5.8% of all newly-diagnosed ESRD patients (incident ESRD patients) in North Carolina’s Network 6 were under the age of 35.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race or gender. However, a direct comparison to the applicant’s 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.

According to the CMS website, in 2008, about 95% of dialysis patients were covered by Medicare. About 25% of the Medicare-covered patients had employer group health plans as primary insurance, with Medicare as the secondary payer. Also, the CMS website states:

*“Although the ESRD population is less than 1% of the entire U.S. population, it continues to increase at a rate of 3% per year and includes people of all races, age groups, and socioeconomic standings. ...*

*Almost half (46.6%) of the incident patients in 2004 were between the ages of 60 and 79. These distributions have remained constant over the past five years. While the majority of dialysis patients are White, ESRD rates among Blacks and Native Americans are disproportionately high. While Blacks comprise over 12% of the national population, they make up 36.4% of the total dialysis prevalent population. In 2004 males represented over half of the ESRD incident (52.6%) and prevalent (51.9%) populations.”*

Additionally, the United States Renal Data System, in its 2012 USRDS Annual Data Report provides these national statistics for FY 2010: *“On December 31, 2010, more than 376,000 ESRD patients were receiving hemodialysis therapy.”* Of the 376,000 ESRD patients, 38.23% were African American, 55.38% were white, 55.65% were male and 44.65% were 65 and older. The report further states:

*“Nine of ten prevalent hemodialysis patients had some type of Medicare coverage in 2010, with 39 percent covered solely by Medicare, and 32 percent covered by Medicare/Medicaid. ... Coverage by non-Medicare insurers continues to increase in the dialysis population, in 2010 reaching 10.7 and 10.0 percent for hemodialysis and peritoneal dialysis patients, respectively.”*

The report provides 2010 ESRD spending by payor, as follows:

ESRD SPENDING BY PAYOR*		
PAYOR	SPENDING IN BILLIONS	% OF TOTAL SPENDING
Medicare Paid	\$29.6	62.32%
Medicare Patient Obligation	\$4.7	9.89%
Medicare HMO	\$3.4	7.16%
Non-Medicare	\$9.8	20.63%

\*Source: 2012 United States Renal Data System (USRDS) Annual Data Report, page 340.

The Southeastern Kidney Council (SKC) provides 2011 Incident ESRD patient data by age, race and gender for Network 6, as shown below.

NUMBER AND PERCENT OF DIALYSIS PATIENTS BY AGE, RACE, AND GENDER*		
	# OF ESRD PATIENTS	% OF DIALYSIS POPULATION
<b>Age</b>		
0-19	89	1.0%
20-34	451	4.8%
35-44	773	8.3%
45-54	1529	16.4%
55-64	2370	25.4%
65-74	2258	24.2%
75+	1872	20.0%
<b>Gender</b>		
Female	4,237	45.35%
Male	5,105	54.65%
<b>Race</b>		
African-American	5,096	54.55%
White	4,027	43.11%
Other	219	2.3%



Total	9,342	100.0%
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\*Source: SKC Network 6, which includes North Carolina, South Carolina and Georgia.

The applicant demonstrates that medically underserved populations currently have adequate access to services available 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

In Section VI.1(f), page 37, the applicant states, “*DC of Hoke County has no obligation under any applicable federal regulation to provide uncompensated care, community service or access by minorities and handicapped persons...*” In Section VI.6(a), page 39, the applicant states “*There have been no civil rights equal access complaints filed within the last five years.*” 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(c), page 36, the applicant provides the projected payor mix for the proposed dialysis services at the facility. The applicant projects no change from the current payor mix. The applicant projects 87.9% of all in-center patients will have some or all of the services paid for by Medicare and Medicaid; and 2.8% of all in-center patients will have services paid for by the VA.

DC HOKE COUNTY HISTORICAL PAYOR MIX	
PAYOR SOURCE	PERCENTAGE
Medicare	36.1%
Medicaid	4.6%
Medicare/Medicaid	24.1%
Commercial Insurance	9.3%
VA	2.8%
Medicare/Commercial	23.1%
Total	100.0%

In Section VI.2, page 38, the applicant states the facility is currently designed and constructed to accommodate handicapped persons, and will not change as a result of this station addition.

The applicant demonstrates that the elderly and medically underserved populations will continue to have adequate access to the proposed dialysis services. 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, pages 38 - 39, the applicant describes the range of means by which patients will have access to the proposed dialysis services. The information provided in Section VI.5 is reasonable and credible and supports a finding of conformity with 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.

NC

In Section V.3, page 33, the applicant states DC Hoke County has existing clinical training agreements with Education Corporation of America. Exhibit 12 contains a copy of an existing agreement between DaVita and Education Corporation of America to provide opportunities for nursing students to use DC Hoke County as a clinical training site. However, the training program specified does not appear to have a program “in the area” of Hoke County. The nearest program, according to the Education Corporation of America website, is in Guilford County, approximately 1.5 hours north of Hoke County. The applicant does not adequately demonstrate that the facility will accommodate the clinical needs of health professional training programs in the proposed service area. Therefore, the application is not 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

Total Renal Care of North Carolina, LLC d/b/a DC Hoke County proposes to add one dialysis station to its existing facility by relocating one existing station from DC Richmond County, for a total of 28 in-center dialysis stations at DC Hoke County and 29 in-center dialysis stations at DC Richmond County upon project completion.

The July 2014 SDR shows that, at the time the application was submitted, there was one operational dialysis facility located in Hoke County, and one facility that was approved but not yet operational. Both facilities are operated by Total Renal Care of North Carolina, LLC. In this application, the applicant is applying to relocate one dialysis station from an under-utilized facility in Richmond County, a contiguous county. Richmond County has 2 ESRD facilities. Both are operated by Total Renal Care of North Carolina, LLC. However, the application is not conforming to Policy ESRD-2 and is thus not conforming to Criterion (1). See discussion at Criterion (1) which is incorporated herein by reference.

The following table identifies the existing dialysis facilities located in Hoke and Richmond Counties, as reported in the July 2014 SDR:

Facility	Location	Utilization
Hoke County		
Dialysis Care of Hoke County	Raeford	91.67%
Lumbee River Dialysis	Raeford	0.00%*
Richmond County		
Dialysis Care of Richmond County	Hamlet	86.11%
Sandhills Dialysis	Rockingham	62.50%

\*This facility is not yet developed

The applicant adequately demonstrates the need for one additional station at DC Hoke County based on the number of in-center patients it proposes to serve. The July 2014 SDR reports that as of December 31, 2013, DC Hoke was operating at 92% capacity, with 110 patients dialyzing on 30 stations [ $110 / 30 = 3.67$ ;  $3.67 / 4 = 0.9167$ ]. The target utilization is 80% or 3.2 patients per station per week as of the end of the first operating year of the facility, pursuant to 10A NCAC 14C .2203(b).

In Section V.7, page 34, the applicant states that the proposed facility expansion is not intended to be a competitive venture; rather, a response to the needs of the facility and patients. Total Renal Care of North Carolina, LLC is the only provider of dialysis services in Hoke County.

See also Sections II, III, V, VI and VII, in which the applicant discusses the cost-effectiveness, quality and access to the proposed services.

The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that relocating one dialysis station from DC Richmond County to DC Hoke County would have a positive impact on cost-effectiveness, quality and access to the proposed service because:

- The applicant adequately demonstrates the need to add one dialysis station to DC Hoke County, for a total of 28 certified in-center dialysis stations upon completion of the proposed project. The applicant also demonstrates that the proposed project is a cost-effective alternative to meet the need to provide additional access to DC Hoke County dialysis patients;
- The applicant adequately demonstrates it will continue to provide quality services. The information regarding staffing provided in Section VII is reasonable and credible and demonstrates adequate staffing for the provision of quality care services in accordance with 42 C.F.R., Section 494 (formerly 405.2100). The information regarding ancillary and support services and coordination of services with the existing health care system in Sections V.1, V.2, V.4, V.5 (pages 31 - 34 ), and VII (pages 40 - 43), and referenced exhibits is reasonable and credible and demonstrates the provision of quality care.
- The applicant adequately demonstrates it will continue to provide adequate access to medically underserved populations. In Section VI.1, page 35, the applicant states:

*“DC of Hoke County, by policy, has always made dialysis services available to all residents in its service area without qualifications. We have served and will continue to serve without regard to race, sex, age, handicap, or ethnic and socioeconomic groups of patients in need of dialysis regardless of their ability to pay.”*

In Section VI, pages 35 – 39, the applicant explains that medically underserved populations will continue to have adequate access to DC Hoke County dialysis services.

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 at DC Hoke County. 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. Furthermore, according to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, DC Richmond County 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.
- (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 proposal is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services in 10A NCAC 14C .2200. The specific findings are discussed below.

#### **10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT**

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

- (1) *Utilization rates;*  
-C- In Sections III and IV, pages 22 and 29, the applicant provides the utilization rates for DC Hoke County.
- (2) *Mortality rates;*  
-C- In Section IV.2, page 29, the applicant states the mortality rates were 4.4%, 11.8% and 12.8% in 2011, 2012 and 2013, respectively.
- (3) *The number of patients that are home trained and the number of patients on home dialysis;*  
-NA- In Section IV.3, page 29, the applicant states those patients who are candidates for home training are referred to Dialysis Care of Moore County. In Exhibit

11, the applicant provides a copy of the home training agreement currently in place.

- (4) *The number of transplants performed or referred;*  
-C- In Section IV.4, page 30, the applicant states DC Hoke County referred 14 patients for transplant evaluation in 2013. The applicant states one transplant was performed in 2013.
- (5) *The number of patients currently on the transplant waiting list;*  
-C- In Section IV.5, page 30, the applicant states DC Hoke County has seven patients currently on the transplant waiting list.
- (6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*  
-C- In Section IV.6, page 30, the applicant states that there were 205 total hospital admissions in 2013, 72 of which were dialysis related and 133 that were non-dialysis related.
- (7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during last calendar year.*  
-C- In Section IV.7, page 30, the applicant states that there was one patient with AIDS dialyzing at DC Hoke County as of December 31, 2013.

*(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:*

- (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.*  
-NA- DC Hoke County is an existing facility.
- (2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with 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.

-NA- DC Hoke County is an existing facility.

(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*

-NA- DC Hoke County is an existing facility.

(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*

-C- See Exhibit 8 for a copy of the policies and procedures for back-up electrical service in the event of a power outage for DC Hoke County.

(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.*

-NA- DC Hoke County is an existing facility.

(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- In Section XI.6(g), page 61, the applicant states, “*Dialysis Care of Hoke County has and will continue to operate within the applicable laws and regulations pertaining to staffing and fire safety equipment, physical environment and other relevant health safety requirements.*”

(7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*

-C- In Section II.1, pages 16 - 17, and Section III.7, pages 25 - 26, the applicant provides the methodology and assumptions to project patient origin as presented in the following table:

COUNTY	OPERATING YEAR 1	OPERATING YEAR 2	COUNTY PATIENTS AS PERCENT OF TOTAL	
	IN-CTR.	IN-CTR.	YEAR 1	YEAR 2
Hoke	80	85	86.9%	87.6%
Cumberland	2	2	2.2%	2.1%
Moore	1	1	1.1%	1.0%
Robeson	9	9	9.8%	9.3
Total	92	97	100.0%	100.0%

The discussion regarding patient origin found in Criterion (3) is incorporated herein by reference.

(8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*

-NA- DC Hoke County is an existing facility.

(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 rate for such services.*

-C- In Section II.1, page 14, the applicant states, *“Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Hoke County 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.”*

#### **10A NCAC 14C .2203 PERFORMANCE STANDARDS**

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

-NA- DC Hoke County does not propose to establish a new End Stage Renal Disease facility.

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

-C- DC Hoke County projects 3.2 patients per station per week as of the end of the first operating year. Assumptions are provided in Section II.1, pages 15 - 16, and Section III.7, pages 25 - 26. The discussion regarding need found in Criterion (3) is incorporated herein by reference.

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

-C- The applicant provides all assumptions, including the methodology by which patient utilization is projected in Section II.1, pages 15 - 16, and Section III.7, pages 25 - 26. The discussion regarding patient utilization found in Criterion (3) is incorporated herein by reference.



## 10A NCAC 14C .2204 SCOPE OF SERVICES

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

- (1) *diagnostic and evaluation services;*  
-C- In Section V.1, page 31, the applicant states patients will receive diagnostic and evaluation services from FirstHealth Moore Regional Hospital.
- (2) *maintenance dialysis;*  
-C- In Section V.1, page 31, the applicant states patients will receive maintenance dialysis services at the facility.
- (3) *accessible self-care training;*  
-C- On page 31 the applicant states patients are referred to Dialysis Care of Moore County for self-care training for dialysis.
- (4) *accessible follow-up program for support of patients dialyzing at home;*  
-C- In Section V.2, page 32 the applicant states those patients desiring home dialysis training and support will be served by Dialysis Care of Moore County.
- (5) *x-ray services;*  
-C- In Section V.1, page 31, the applicant states x-ray services will be provided by FirstHealth Moore Regional Hospital.
- (6) *laboratory services;*  
-C- In Section V.2, page 32, the applicant states laboratory services will be provided by FirstHealth Moore Regional Hospital; and on page 31 the applicant states that Dialysis Laboratories will provide routine, special and immunological laboratory services.
- (7) *blood bank services;*  
-C- In Section V.1, page 31, the applicant states blood bank services will be provided by FirstHealth Moore Regional Hospital, and on page 31, the applicant states that Dialysis Laboratories will provide routine, special and immunological laboratory services.
- (8) *emergency care;*  
-C- In Section V.1, page 31, the applicant states emergency care services will be provided by FirstHealth Moore Regional Hospital.
- (9) *acute dialysis in an acute care setting;*  
-C- In Section V.1, page 31, the applicant states acute dialysis services will be provided by FirstHealth Moore Regional Hospital.
- (10) *vascular surgery for dialysis treatment patients;*

-C- In Section V.1, page 31, the applicant states vascular surgery services will be provided by FirstHealth Moore Regional Hospital.

(11) *transplantation services;*

-C- In Section V.1, page 31, the applicant states transplantation services will be provided by Carolinas Medical Center.

(12) *vocational rehabilitation counseling and services; and*

-C- In Section V.1, page 31, the applicant states vocational rehabilitation counseling and services will be provided by North Carolina Division of Vocational Rehabilitation Services.

(13) *transportation.*

-C- In Section V.1, page 31, the applicant states transportation services will be provided by local transportation agencies.

#### **10A NCAC 14C .2205                      STAFFING AND STAFF TRAINING**

(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, on page 40, the applicant states that all staffing requirements will be met as stated in 42 C.F.R. Section 494 (formerly 405.2100). The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

(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- In Exhibit 17 the applicant provides a copy of the applicant's training program outline for nurses and technicians in dialysis techniques at the facility.