

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 16, 2016

Findings Date: December 16, 2016

Project Analyst: Tanya S. Rupp

Team Leader: Lisa Pittman

Project ID #: N-11253-16

Facility: Dialysis Care of Hoke County

FID #: 945165

County: Hoke

Applicant: Total Renal Care of North Carolina, LLC

Project: Add ten stations to existing facility for a total of 24 stations following completion of this project, Project ID# N-11077-15 (relocate four stations to Maxton Dialysis) and Project ID# N-11192-16 (relocate ten stations to East Hoke County Dialysis).

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.

C

The applicant, Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Hoke County (“DC Hoke County”), proposes to add ten stations to the existing facility for a total of 24 in-center stations upon completion of this project, Project ID #N-11077-15 (relocate four stations to Maxton Dialysis) and Project ID# N-11192-16 (relocate ten stations to East Hoke County Dialysis).

Need Determination

The 2016 State Medical Facilities Plan (2016 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations.

According to the July 2016 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of one dialysis station in Hoke County. Therefore, there is no county need for additional stations in Hoke County. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology, because the utilization rate reported for Dialysis Care of Hoke County in the July 2016 SDR is 3.7 patients per station. This utilization rate was calculated based on 104 in-center dialysis patients and 28 certified dialysis stations as of December 31, 2015 (104 patients / 28 stations = 3.71 patients per station). Application of the facility need methodology indicates that additional stations are needed for this facility, as illustrated in the following table:

OCTOBER 1 REVIEW-JULY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/15		92.9%
Certified Stations		28
Pending Stations		0
Total Existing and Pending Stations		28
In-Center Patients as of 12/31/15 (July 2016 SDR) (SDR2)		104
In-Center Patients as of 6/30/15 (Jan 2016 SDR) (SDR1)		95
Step	Description	Result
	Difference (SDR2 - SDR1)	9
(i)	Multiply the difference by 2 for the projected net in-center change	18
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/15	0.1895
(ii)	Divide the result of Step (i) by 12	0.0158
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/14 until 12/31/15)	0.1895
(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	123.7053
(v)	Divide the result of Step (iv) by 3.2 patients per station	38.6579
	and subtract the number of certified and pending stations to determine the number of stations needed	10.6579

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is 11, rounding up to the nearest whole number. Step (C) of the facility need methodology states “*The facility may apply to expand to meet the need established ..., up to a maximum of ten stations.*” The applicant proposes to add ten new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policies

Policy GEN-3: Basic Principles, page 39, of the 2016 SMFP is applicable to this review. *Policy GEN-3* states:

“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

The applicant addresses Policy GEN-3 as follows:

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section B.4(a), pages 9-10, and in Exhibits B-4 and K-1(g). The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality in the delivery of dialysis services.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section B.4(b), page 10, Section C.3, pages 13 - 15, Section L, pages 43 - 47, and Exhibit L-3. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access to dialysis services.

Maximize Healthcare Value – The applicant describes how it believes the proposed project would maximize healthcare value in Section B.4(c), page 11, Section G, page 29, and Section N.1, page 49. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value for dialysis services.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need as identified by the applicant. The application is consistent with Policy GEN-3.

Conclusion

In summary, the applicant adequately demonstrates that the application is consistent with the facility need determination in the July 2016 SDR and with *Policy GEN-3: Basic Principles*. 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 Dialysis Care of Hoke County (DC Hoke County) proposes to add ten stations to the existing facility for a total of 24 in-center stations upon completion of this project, Project ID #N-11077-15 (relocate four stations to Maxton Dialysis) and Project ID# N-11192-16 (relocate ten stations to East Hoke County Dialysis).

Population to be Served

On page 369, the 2016 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Hoke County. Facilities may also serve residents of counties not included in their service area.

In Section C-8, page 18, the applicant provides the historical patient origin for DC Hoke County for in-center patients as of December 31, 2015, as summarized in the following table:

**Dialysis Care of Hoke County
 Patient Origin as of 12/31/15**

COUNTY	# OF PATIENTS	% OF TOTAL
Hoke	77	74.0%
Robeson	13	12.5%
Scotland	5	4.8%
Other States	4	3.8%
Moore	4	3.8%
Cumberland	1	1.0%
Total	104	100.0%

Totals may not foot due to rounding.

In Section C.1, page 13, the applicant identifies the patient population it proposes to serve for the first two years of operation following project completion, as illustrated in the following table:

**Dialysis Care of Hoke County
 Projected Patient Origin OY 1 and 2**

COUNTY	OY 1 (CY 2018)		OY 2 (CY 2019)	
	# OF PATIENTS	% OF TOTAL	# OF PATIENTS	% OF TOTAL
Hoke	60	72.3%	62	72.9%

Robeson	10	12.0%	10	11.8%
Scotland	5	6.0%	5	5.9%
Other States	4	4.8%	4	4.7%
Moore	4	4.8%	4	4.7%
Total	83	100.0%	85	100.0%

Totals may not foot due to rounding.

See pages 13 - 15 for the assumptions and data used to project patient origin.

The applicant adequately identifies the population to be served.

Analysis of Need

In Section B.1, page 7, the applicant provides a table to show the application is filed pursuant to the facility need methodology in the 2016 SMFP, which utilizes data from the July 2016 SDR. The applicant proposes to add ten dialysis stations to DC Hoke County for a total of 24 certified stations upon completion of this project, Project ID #N-11077-15 and Project ID# N-11192-16.

In Section C.1, pages 13 – 14, the applicant provides the assumptions and methodology to support its need, which are summarized below:

- The applicant begins its patient census with 104 patients, as reported in the July 2016 SDR.
- The applicant states 77 of those patients are residents of Hoke County.
- In Project ID# N-11077-15 the applicant was approved to relocate four stations from DC Hoke County. The applicant projected that four patients would transfer their care when that facility is certified in January 2017.
- In Project ID# N-11192-16, the applicant was approved to develop a new facility and relocate ten stations from DC Hoke County. The applicant projected that 27 in-center patients would transfer their care to the new facility when that facility is certified in January 2018.
- The applicant projects growth of the Hoke County patients using the 3.3% Hoke County Five Year Average Annual Change Rate (AACR) as published in the July 2016 SDR. The applicant calculates growth beginning January 2016 through December 31, 2019.
- The applicant adds the patients who reside outside of Hoke County after projecting growth of the Hoke County patient population, and repeats this for each interim and project year.
- The applicant projects the stations proposed in this application will be certified on December 31, 2017; therefore, the first project year is CY 2018 and the second project year is CY 2019.

Projected Utilization

In Section C.1, page 14, the applicant projects the following utilization for DC Hoke County:

	DATE	# SA PTS.	GROWTH RATE	# SA YEAR END PTS	# PTS FROM OUT OF SA	TOTAL # PTS YEAR END	DATE
Current Year	1/1/16	77	1.033	79.541	27	106.541	12/31/16
Interim	1/1/17	79.541	1.033	82.165	27 - 4 = 23	105.166	12/31/17
OY 1	1/1/18	82 - 23 = 59	1.033	60.947	23 - 4 = 19	79.947	12/31/18
OY 2	1/1/19	60.947	1.033	62.958	19	81.958	12/31/19

The applicant rounds down to the nearest whole number and projects to serve 79 in-center patients on 24 stations or 3.29 patients per station per week [79 / 24 = 3.29] by the end of Operating Year 1, and 81 in-center patients or 3.38 patients per station per week [81 / 24 = 3.38] by the end of Operating Year 2 for the proposed facility. This takes into account the patients projected to transfer their care to other TRC facilities as described above pursuant to the approved projects (Project ID #N-11077-15 and Project ID #N-11192-16). This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

The applicant adequately demonstrates that projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

Access to Services

In Section C.3, page 15, the applicant states that by policy, the proposed services will be available to all persons without qualifications, including racial and ethnic minorities, women, low-income persons, persons with disabilities, elderly and “other underserved persons.”

In addition, in Section L.1, page 44 the applicant projects that 89.3% of the patients who will dialyze at DC Hoke County will be covered by either Medicare or Medicaid. In Section L.1, page 44, the applicant states that its projected payor mix is based on the payor mix for the last full operating year for DC Hoke County. The applicant adequately demonstrates the extent to which all residents of the area, including the medically underserved, are likely to have access to the proposed services.

Conclusion

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need that population has for the proposed project and the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services. 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.

NA

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

CA

In Section E.1, page 22, the applicant discusses the alternatives considered prior to submitting this application, summarized as follows:

- Maintain the Status Quo – the applicant states that this alternative was dismissed considering the growth rate at DC Hoke County.
- Relocate Dialysis Stations from a Different DaVita Facility – The applicant states the only other dialysis facility in Hoke County (Lumbee River Dialysis) is operating at less than 80% capacity; however, Basic Principle number 2 in Chapter 14 of the 2016 State Medical Facilities Plan requires new dialysis facilities to have “*a projected need for at least 10 stations (or 32 patients at 3.2 patients per station) to be cost effective and to assure quality of care.*” Lumbee River Dialysis has ten dialysis stations and thus is not eligible to relinquish any stations; therefore the applicant determined that this is not the most effective alternative to meet the identified need for additional dialysis stations.

After considering the above alternatives, the applicant states that applying for ten stations at DC Hoke County pursuant to the facility need methodology is the most effective alternative to meet the identified need for additional stations to serve the dialysis patients in Hoke County.

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

In summary, the applicant adequately demonstrates that this proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

- 1. Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Hoke County shall materially comply with all representations made in the certificate of need application.**
- 2. Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Hoke County shall add no more than 10 dialysis stations to the existing facility for a total of 24 dialysis stations following completion of this project, Project ID# N-11077-15 (relocate four stations to Maxton Dialysis) and Project ID #N-11192-16 (relocate ten stations to East Hoke County Dialysis).**

3. **Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Hoke County shall install plumbing and electrical wiring through the walls for no more than 10 dialysis stations, which shall include any isolation or home hemodialysis stations.**
 4. **Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Hoke County shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to add ten stations to the existing facility for a total of 24 stations following completion of this project, Project ID# N-11077-15 (relocate four stations to Maxton Dialysis) and Project ID# N-11192-16 (relocate ten stations to East Hoke County Dialysis).

Capital Costs and Working Capital Costs

In Section F.1, page 23, the applicant states there is no capital cost associated with this project. In Section F.10 and Section F.11, pages 25 - 26, the applicant states there will be no start-up or initial operating expenses associated with this project.

Financial Feasibility

In Section R, Form C of the pro formas, the applicant provides its allowable charge per treatment for each payment source and provides its operating expense and revenue assumptions in Forms A-C.

The applicant projects revenues in Section R, Form B of the pro formas, and operating expenses in Section R, Form A of the pro formas, summarized in the table below:

DC Hoke County		
	OY 1 (CY 2018)	OY 2 (CY 2019)
Total Net Revenue	\$3,182,576	\$3,244,017
Total Operating Expenses	\$3,031,343	\$3,097,513
Net Profit	\$ 151,233	\$ 146,504

The applicant projects that revenues will exceed operating expenses in each of the first two operating years.

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section R, the financial section of the application, for the assumptions used regarding costs and charges. The discussion regarding utilization projections found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates the availability of sufficient funds for the operating needs of the project and that the financial feasibility of the proposal is based upon reasonable and adequately supported assumptions regarding projected utilization, revenues (charges) and operating costs.

Conclusion

In summary, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon 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 (DC Hoke County) proposes to add ten stations to the existing facility for a total of 24 in-center stations upon completion of this project, Project ID #N-11077-15 (relocate four stations to Maxton Dialysis) and Project ID# N-11192-16 (relocate ten stations to East Hoke County Dialysis).

On page 369, the 2016 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Hoke County. Facilities may also serve residents of counties not included in their service area.

The January 2016 SDR indicates there are 2 dialysis facilities in Hoke County, both of which are owned and operated by Total Renal Care of North Carolina, LLC

DC Hoke County was operating above capacity at 92.86% as of December 31, 2015. Although Lumbee River Dialysis is operating at 57.50%, it is located in Red Springs in the southern part of the county, and serves a population that resides closer to that facility.

The applicant is not increasing the number of dialysis stations in Hoke County, rather it is adding 10 stations back to a facility that is relocating ten stations to East Hoke County Dialysis when Project ID# N-11192-16 is developed.

In Section C.1, pages 13 - 15, the applicant provides reasonable projections for the in-center patient population it proposes to serve. The applicant's growth projections are based on the Hoke County Five Year AACR as published in the July 2016 SDR.

The applicant adequately demonstrates the need to add ten stations to the existing facility. The discussion on analysis of need found in Criterion (3) is incorporated herein by reference.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities 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 H.1, page 30, the applicant provides the current staffing for the facility and the projected staffing following the addition of ten dialysis stations. The following table illustrates current and projected staffing at DC Hoke County:

DC Hoke County, Current and Projected Staffing

POSITION	CURRENT FTES	# FTES TO BE ADDED	TOTAL FTE POSITIONS
Registered Nurse	4.0	0.0	4.0
Patient Care Technician	11.0	0.0	11.0
Administrator	1.0	1.0	2.0
Dietician	1.0	0.0	1.0
Social Worker	1.0	0.0	1.0
Administrative Assistant	1.0	0.0	1.0
Biomedical Technician	1.0	0.0	1.0
Total	20.0	1.0	21.0

Source: Application page 30

In Section H.2, page 31, the applicant states that the Medical Director for DC Hoke County will be Dr. John Shepherd. In Exhibit I-3, the applicant provides a letter signed by Dr. Shepherd, dated August 15, 2016, confirming his commitment to continue to serve as Medical Director.

The applicant documents the availability of adequate health manpower and management personnel, including the Medical Director, for the 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 Section I, pages 34 - 36, the applicant includes a list of providers of the necessary ancillary and support services to be provided for the patients who dialyze at the facility. The applicant provides documentation regarding coordination with the existing health care system in Exhibits I-1 and I-3, including letters from DaVita Laboratory Services, Inc. and several nephrologists. The information in Section I and Exhibits I-1 and I-3 is reasonable and adequately 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 L.7, page 47, the applicant provides the historical payor mix for DC Hoke County for CY 2015. The historical payor mix is illustrated as follows:

**DC Hoke County
 Payor Mix CY 2015**

PAYOR TYPE	% OF TOTAL PATIENTS
Medicare	41.8%
Medicaid	9.5%
Commercial Insurance	6.9%
Medicare/Commercial	14.3%
Medicare/Medicaid	23.7%
VA	3.8%
Total	100.0%

Totals may not foot due to rounding

As the table above indicates, 89.3% of DC Hoke County's patients were covered by Medicare or Medicaid in CY 2015. In addition, the applicant describes its admission and financial policies in Section L.3, pages 44 – 45, and provides a copy of its admission policy which states that patients will be admitted “*without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability*” in Exhibit L-3.

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

Percent of Population						
County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
Hoke	8%	51%	59%	20%	11%	21%
Robeson	13%	52%	73%	33%	13%	25%
Cumberland	11%	51%	55%	18%	11%	16%

Statewide	15%	51%	36%	17%	10%	15%
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Source: <http://www.census.gov/quickfacts/table>, 2014 Estimate as of December 22, 2015.

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

**"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

The *Southeastern Kidney Council Network 6 Inc. Annual Report* provides prevalence data on North Carolina dialysis patients by age, race, and gender on page 59, summarized as follows:

Number and Percent of Dialysis Patients by Age, Race, and Gender 2014		
	# of ESRD Patients	% of Dialysis Population
Age		
0-19	52	0.3%
20-34	770	4.8%
35-44	1,547	9.7%
45-54	2,853	17.8%
55-64	4,175	26.1%
65+	6,601	41.3%
Gender		
Female	7,064	44.2%
Male	8,934	55.8%
Race		
African-American	9,855	61.6%
White	5,778	36.1%
Other, inc. not specified	365	2.3%

Source:<http://www.esrdnetwork6.org/utills/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older and over 63% were non-Caucasian. (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59*).

The applicant demonstrates that it currently provides adequate access to medically underserved populations. 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 applicants;

C

In Section L.3(d) page 46, the applicant states,

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

In Section L.6, page 46, the applicant states that there have been no civil rights equal access complaints filed within the last five years against the existing facility or any facilities owned by the parent corporation.

The application is conforming to this criterion.

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section L.1, page 44, the applicant states that the projected payor mix is based on historical payor mix for DC Hoke County for the last full operating year, illustrated as follows:

**DC Hoke County
Payor Mix OY 2**

PAYOR TYPE	% OF TOTAL PATIENTS
Medicare	41.8%
Medicaid	9.5%
Commercial Insurance	6.9%
Medicare/Commercial	14.3%
Medicare/Medicaid	23.7%
VA	3.8%
Total	100.0%

Totals may not foot due to rounding

The applicant projects that 89.3% of its patients will be covered by Medicare or Medicaid. In Section L, page 44, the applicant states projected payor mix is based on the historical payor mix at DC Hoke County.

The applicant demonstrates that medically underserved populations will have adequate access to the proposed 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 L.4, page 46, the applicant states that patients will have access to the facility for dialysis services upon referral from a Nephrologist with admitting privileges at the facility. Patients who contact the facility directly or indirectly will be referred to *“a qualified nephrologist for evaluation and subsequent admission if it were found to be medically necessary....”* In Exhibit I-3, the applicant provides letters of support from area Nephrologists.

The applicant adequately demonstrates that it will offer a range of means by which patients will have access to the proposed 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

In Section M.1, page 48, the applicant states that it has offered DC Hoke County as a clinical training site for nursing students from Sandhills Community College – Hoke Center. A copy of a letter sent by the applicant to the college, dated August 16, 2016, is included in Exhibit M-2.

The information provided in Section M.1 and Exhibit M-2 is reasonable and adequately 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

Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Hoke County (DC Hoke County) proposes to add ten stations to the existing facility for a total of 24 in-center stations upon completion of this project, Project ID #N-11077-15 (relocate four stations to Maxton Dialysis) and Project ID# N-11192-16 (relocate ten stations to East Hoke County Dialysis).

On page 369, the 2016 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Hoke County. Facilities may also serve residents of counties not included in their service area.

The January 2016 SDR indicates there are 2 dialysis facilities in Hoke County, both of which are owned and operated by Total Renal Care of North Carolina, LLC

DC Hoke County was operating above capacity at 92.86% as of December 31, 2015. Although Lumbee River Dialysis is operating at 57.50%, it is located in Red Springs in the southern part of the county, and serves a population that resides closer to that facility.

The applicant is not increasing the number of dialysis stations in Hoke County, rather it is adding 10 stations back to a facility that is relocating ten stations to East Hoke County Dialysis when Project ID #N-11192-16 is developed.

In Section N.1, page 50, the applicant states that addition of the ten stations proposed in this application will not have any effect on competition in Hoke County. TRC is the only provider of dialysis services in Hoke County.

See also Sections B, C, D, F, and L where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

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

- The applicant adequately demonstrates the need for the proposed project and that it is a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates that DaVita will continue to provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.

- The applicant demonstrates that DaVita will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (3), (3a) and (13) are incorporated herein by reference.

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

In Section O, page 50, the applicant describes the methods by which DC Hoke County will ensure the provision of quality care. In Exhibit O-3, the applicant provides a list of four dialysis facilities operated by the applicant that were not in compliance with Medicare conditions of participation during the 18 months prior to submission of the application. The applicant provides documentation in Exhibit L-3 to confirm that each facility is back in compliance as of the date of the application.

Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. The application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

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

10 NCAC 14C .2203 PERFORMANCE STANDARDS

.2203(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station

per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.

-NA- The applicant is not proposing to establish a new end stage renal disease facility.

.2203(b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.

-C- In Section C-1, pages 13 – 15 the applicant demonstrates the need for ten additional stations at DC Hoke County based on 79 patients dialyzing on 24 in-center stations as of the end of the first operating year [$79 / 24 = 3.29$; $3.29 / 4 = 82.3\%$].

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

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