

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: January 12, 2016

Findings Date: January 12, 2016

Project Analyst: Tanya S. Rupp

Team Leader: Fatimah Wilson

Project ID #: H-11251-16

Facility: Sandhills Dialysis

FID #: 090624

County: Richmond

Applicant: Total Renal Care of North Carolina, LLC

Project: Add six stations to existing facility for a total of 22 stations upon project completion

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

The applicant, Total Renal Care of North Carolina, LLC d/b/a Sandhills Dialysis proposes to add six stations to the existing facility for a total of 22 in-center stations upon project completion.

#### **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 no need for additional dialysis stations in Richmond 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 Sandhills

Dialysis in the July 2016 SDR is 3.6 patients per station. This utilization rate was calculated based on 58 in-center dialysis patients and 16 certified dialysis stations as of December 31, 2015 (58 patients / 16 stations = 3.62 patients per station). Application of the facility need methodology indicates that additional stations are needed for this facility, as illustrated in the following table:

<b>OCTOBER 1 REVIEW-JULY 2016 SDR</b>		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/15		90.6%
Certified Stations		16
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>16</b>
In-Center Patients as of 12/31/15 (July 2016 SDR) (SDR2)		58
In-Center Patients as of 6/30/15 (Jan 2016 SDR) (SDR1)		53
Step	Description	Result
	Difference (SDR2 - SDR1)	5
(i)	Multiply the difference by 2 for the projected net in-center change	10
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/15	0.1887
(ii)	Divide the result of Step (i) by 12	0.0157
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/14 until 12/31/15)	0.1887
(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	68.9434
(v)	Divide the result of Step (iv) by 3.2 patients per station	21.5448
	and subtract the number of certified and pending stations to determine the number of stations needed	5.5448

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is six, 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 six 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, Exhibits B-4 and K-1(g) and Section N.1, page 48. 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, page 15, Section L, pages 42 - 45, and Exhibit L-3 and Section N.1, page 48. 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 and Section N.1, page 48. 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 need for six additional dialysis stations 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 Sandhills Dialysis proposes to add six stations to the existing facility for a total of 22 in-center stations upon project completion.

**Patient Origin**

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 is Richmond County. Facilities may also serve residents of counties not included in their service area.

In Section C-8, page 17, the applicant provides the in-center patient origin for Sandhills Dialysis as of December 31, 2015, as summarized in the following table:

**Sandhills Dialysis  
 Patient Origin as of 12/31/15**

COUNTY	# OF PATIENTS	% OF TOTAL
Richmond	56	97.0%
Other States	2	3.0%
<b>Total</b>	<b>58</b>	<b>100.0%</b>

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

**Sandhills Dialysis  
 Projected Patient Origin OY 1 and 2**

COUNTY	OY 1 (CY 2018)		OY 2 (CY 2019)	
	# OF PATIENTS	% OF TOTAL	# OF PATIENTS	% OF TOTAL
Richmond	70	97.2%	76	97.4%
Other States	2	2.8%	2	2.6%
<b>Total</b>	<b>72</b>	<b>100.0%</b>	<b>78</b>	<b>100.0%</b>

Totals may not foot due to rounding.

See pages 13 - 14 for the assumptions and methodology used to project patient origin.

The applicant adequately identifies the population to be served.

**Analysis of Need**

In Section B.2, page 7, the applicant provides a table to show the application is filed pursuant to the facility need methodology outlined in the 2016 SMFP, utilizing data from the July 2016 SDR. The applicant proposes to add six dialysis stations to Sandhills Dialysis for a total of 22 certified stations upon project completion.

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

- The applicant notes the facility was dialyzing 58 in-center patients on 16 certified dialysis stations as of December 15, 2015, as reported in the July 2016 SDR.
- The applicant states 56 of those patients are residents of Richmond County.
- The applicant uses the 8.2% Richmond County Five Year Average Annual Change Rate (AACR) reported in the July 2016 SDR to project growth at the facility.
- The applicant states Operating Year one is projected to begin January 1, 2018, and Operating Year two is projected to begin January 1, 2019. Operating Years are calendar years, as reported by the applicant on page 13.
- The applicant adds the two patients who reside outside of Richmond County after projecting growth of the Richmond County patient population, and repeats this for each interim and project year.
- The applicant projects growth beginning January 1, 2016 and ending December 31, 2019.

Projected Utilization

In Section C.1, page 14, the applicant projects the following in-center utilization for Sandhills Dialysis:

	DATE	# SA PTS.	GROWTH RATE	# SA YEAR END PTS	# PTS FROM OUT OF SA	TOTAL # PTS YEAR END	DATE
Current Year	1/1/16	56	1.082	60.592	2	62.592	12/31/16
Interim	1/1/17	60.592	1.082	65.561	2	67.561	12/31/17
OY 1	1/1/18	65.561	1.082	70.937	2	72.937	12/31/18
OY 2	1/1/19	70.937	1.082	76.753	2	78.753	12/31/19

The applicant rounds down to the nearest whole number and projects to serve 72 in-center patients on 22 stations or 3.27 patients per station per week [72 / 22 = 3.27] by the end of Operating Year 1, and 78 in-center patients or 3.55 patients per station per week [78 / 22 = 3.55] by the end of Operating Year 2 for the facility. The projected utilization for OY 1 exceeds the minimum of 3.2 patients per station per week 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 regard to race, sex, age or handicap. The applicant further

states services will be available to low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, and “*other underserved persons.*”

In addition, in Section L.1, page 43 the applicant projects that 94.8% of the patients who will dialyze at Sandhills Dialysis will be covered by either Medicare or Medicaid. In Section L.1, page 43, the applicant states that its projected payor mix is based on the payor mix for the last full operating year for Sandhills Dialysis. 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 21, 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 Sandhills Dialysis.
- Relocate Dialysis Stations from a Different DaVita Facility – The applicant states that the other dialysis facility in Richmond County (Dialysis Care of Richmond County, a DaVita facility) (DC Richmond County) is operating at 79.63% capacity. The applicant states on page 21 that relocating stations from that facility would negatively impact patients served by that facility. Therefore the applicant determined that this is not the most effective alternative to meet the identified need for additional dialysis stations.

The July 2016 SDR shows that there were three approved but not yet certified stations at Dialysis Care of Richmond County (DC Richmond County) as of December 31, 2015. The January 2017 SDR shows that those stations are currently certified; thus, DC Richmond County is now certified for 30 in-center stations. In addition, the July 2016 SDR shows the Five Year AACR for Richmond County is 8.2%. Given that DC Richmond County was dialyzing 86 in-center patients as of December 31, 2015 as reported in the July 2016 SDR, then with the addition of the three stations, that facility would dialyze 3.1 patients per station per week within 12 months, and 3.4 patients per station per week within 24 months [ $86 \times 1.082 = 93.05$ ;  $93.05 / 30 = 3.10$ .  $93.05 \times 1.082 = 100.68$ ;  $100.68 / 30 = 3.35$ ). Clearly, the patient population at DC Richmond County is growing.

After considering the above alternatives, the applicant states that applying for six stations at Sandhills Dialysis 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 Richmond 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 Sandhills Dialysis shall materially comply with all representations made in the certificate of need application.**
  - 2. Total Renal Care of North Carolina, LLC d/b/a Sandhills Dialysis shall add no more than six dialysis stations to the existing facility for a total of 22 dialysis stations upon project completion.**
  - 3. Total Renal Care of North Carolina, LLC d/b/a Sandhills Dialysis shall install plumbing and electrical wiring through the walls for no more than six dialysis stations, which shall include any isolation or home hemodialysis stations.**
  - 4. Total Renal Care of North Carolina, LLC d/b/a Sandhills Dialysis shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to add six stations to the existing facility for a total of 22 stations upon project completion.

**Capital Costs and Working Capital Costs**

In Section F.1, page 22, the applicant projects \$1,427,686 in capital costs to develop the proposed project. In Sections F.10 - F.12, pages 24 - 25, the applicant projects there will be no start-up expenses or initial operating expenses associated with this project, since the facility is currently operational.

**Availability of Funds**

In Section F.2, page 23, the applicant states it will finance the capital costs with the accumulated reserves and owner's equity of DaVita, parent company to Total Renal Care of North Carolina, LLC.

Exhibit F-1 contains a letter dated September 12, 2016, from the Chief Accounting Officer of DaVita, as the parent company of TRC and also as the guarantor of the funds on behalf of Sandhills Dialysis, which confirms availability and commitment of sufficient cash reserves for the capital costs of \$1,427,686, as well as, "*any other funds that are necessary for the development of the project.*" In Section F.7, page 27, in reference to providing the most recent financial report, the applicant states:

*"Corporate financial statements serve as Exhibit F-7. These statements include a copy of the United States Securities and Exchange Commission Form 10-K for the fiscal year ended December 31, 2015.*

Exhibit F-7 contains DaVita's Securities and Exchange Commission (SEC) Form 10-K for the fiscal year ended December 31, 2014, not 2015, as stated by the applicant. However, the Agency has DaVita's Form 10-K for the year ended December 31, 2015 on file from Project ID #F-11154-16, which documents that as of December 31, 2015, DaVita had \$1,499,116,000 in cash and cash equivalents, \$18,514,875,000 in total assets and \$5,084,172,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates that sufficient funds will be available for the capital and operating needs of the project.

**Financial Feasibility**

The applicant provided pro forma financial statements for the first two years of the project. In the pro forma financial statement (Form B), the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.



**Sandhills Dialysis  
Revenues and Expenses**

	<b>OY 1 (CY 2018)</b>	<b>OY 2 (CY 2019)</b>
Total Treatments	10,303	11,113
Total Gross Revenues (Charges)	\$2,918,238	\$3,148,283
Total Net Revenue	\$2,787,239	\$3,006,916
Total Operating Expenses (Costs)	\$2,627,692	\$2,800,208
<b>Net Profit</b>	<b>\$ 159,277</b>	<b>\$ 206,708</b>

Source: Application Section R, Forms B and C

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 and adequately supported assumptions regarding utilization and revenues (charges and operating costs). Therefore, the application is conforming to this criterion.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

**C**

Total Renal Care of North Carolina, LLC d/b/a Sandhills Dialysis proposes to add six stations to the existing facility for a total of 22 in-center stations upon project completion.

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 Richmond County. Facilities may also serve residents of counties not included in their service area.

The July 2016 SDR indicates there are two dialysis facilities in Richmond County, both of which are owned and operated by Total Renal Care of North Carolina, LLC, as shown in the table below:

FACILITY	LOCATION	# STATIONS	# APPROVED STATIONS*	# PATIENTS	% UTILIZATION
Dialysis Care of Richmond County	Hamlet	27	3	86	79.63%
Sandhills Dialysis	Rockingham	16	0	58	90.63%

\*Stations approved but not yet certified  
Source: Table A, July 2016 SDR

Sandhills Dialysis was operating above capacity at 90.63% as of December 31, 2015. Dialysis Care of Richmond County was operating at 79.63%, with 3.185 patients per station per week. The average utilization of both DaVita dialysis facilities in Richmond County is 85.13%. In Section G, page 28, the applicant states that transferring stations from Dialysis Care of Richmond County would negatively impact the patients who currently dialyze there. Furthermore, the applicant states that while it does propose to increase the inventory of dialysis stations in Richmond County, the increase serves to increase needed capacity rather than duplicate any existing or approved services in the county.

In Section C.1, pages 13 - 14, the applicant provides reasonable projections for the in-center patient population it proposes to serve. The applicant's growth projections are based on the Richmond County Five Year AACR as published in the July 2016 SDR.

The applicant adequately demonstrates the need to add six 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 Richmond 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 29, the applicant provides the current staffing for the facility and the projected staffing following the addition of six dialysis stations. The following table illustrates current and projected staffing at Sandhills Dialysis:

**Sandhills Dialysis Current and Projected Staffing**

POSITION	CURRENT FTEs	# FTEs TO BE ADDED	TOTAL FTE POSITIONS
Registered Nurse	2.0	1.0	3.0
Patient Care Technician	6.0	3.0	9.0
Administrator	1.0	1.0	2.0
Dietician	0.5	0.0	0.5
Social Worker	0.5	0.0	0.5
Administrative Assistant	1.0	0.0	1.0
Biomedical Technician	0.5	0.0	0.5
<b>Total</b>	<b>11.5</b>	<b>5.0</b>	<b>15.5</b>

Source: Application page 29

As shown in the table above, the applicant proposes to add 3.5 full-time equivalent (FTE) positions upon project completion. In Section H.2, page 30, the applicant states that the Medical Director for Sandhills Dialysis will be Dr. Jennifer Stoddard. In Exhibit I-3, the applicant provides a letter signed by Dr. Shepherd, dated August 15, 2016, confirming her commitment to continue to serve as Medical Director. In Section H.3, pages 30 – 31, the applicant describes its method for recruiting and retaining staff.

In Section H.7, page 32, the applicant projects the following direct care staff for the second operating year:

DIRECT CARE POSITIONS	# FTEs	HOURS/YEAR/ FTE	TOTAL ANNUAL FTE HOURS	TOTAL ANNUAL HOURS OF OPERATION	FTE HOURS/HOURS OF OPERATION
RN	3	2,080	6,240	3,120	2
Patient Care Technician	9	2,080	18,720	3,120	6
Total	12	2,080	24,960	3,120	8

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.

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In Section I, pages 33 - 35, the applicant includes a list of providers of the necessary ancillary and support services to be provided for the patients who dialyze at Sandhills Dialysis. 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.

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In Section K.2, page 38, the applicant provides a table to illustrate its plans to renovate and expand the existing facility by 2,148 square feet; from 3,071 square feet to 5,219 square feet. The applicant provides a line drawing of the facility with the six proposed additional stations in Exhibit K. In Section F.1, page 22, the applicant lists the project costs, including \$963,000 for construction and \$464,686 in miscellaneous project costs including water treatment equipment, furniture, architect/engineering fees, and a contingency for a total project cost of \$1,427,686. In Section K.1, pages 37 - 38, the applicant describes its plans for energy-efficiency and water conservation. Costs and charges are described by the applicant in Section R of the application. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference.

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, that energy saving features have been incorporated into the construction plans, and that the construction cost will not unduly increase costs and charges for dialysis services. Therefore, the application is conforming to this criterion.

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

C

In Section L.7, page 46, the applicant provides the historical payor mix for Sandhills Dialysis for CY 2015, as follows:

**Sandhills Dialysis  
Historical Payor Mix CY 2015**

<b>PAYOR TYPE</b>	<b>% OF TOTAL PATIENTS</b>
Medicare	27.6%
Medicaid	1.7%
Commercial Insurance	5.2%
Medicare/Commercial	20.7%
Medicare/Medicaid	44.8%
<b>Total</b>	<b>100.0%</b>

Totals may not foot due to rounding

As the table above indicates, 94.8% of Sandhills Dialysis'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 43 – 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**
Richmond	16%	51%	42%	25%	16%	20%
Statewide	15%	51%	36%	17%	10%	15%

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
<b>Age</b>		
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%
<b>Gender</b>		
Female	7,064	44.2%
Male	8,934	55.8%
<b>Race</b>		
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 45, the applicant states,

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

In Section L.6, page 45, 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 43, 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:

**Sandhills Dialysis  
Projected Payor Mix OY 2**

<b>PAYOR TYPE</b>	<b>% OF TOTAL PATIENTS</b>
Medicare	27.6%
Medicaid	1.7%
Commercial Insurance	5.2%
Medicare/Commercial	20.7%
Medicare/Medicaid	44.8%
<b>Total</b>	<b>100.0%</b>

Totals may not foot due to rounding

The applicant projects that 94.8% of its patients will be covered by Medicare or Medicaid. In Section L, page 43, the applicant states projected payor mix is based on the historical payor mix at Sandhills Dialysis.

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 45, 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 47, the applicant states that it has offered Sandhills Dialysis as a clinical training site for nursing students from Richmond Community College. A copy of a letter sent by the applicant to the college, dated February 2015, 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 Sandhills Dialysis proposes to add six stations to the existing facility for a total of 24 in-center stations upon project completion.

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 Richmond County. Facilities may also serve residents of counties not included in their service area.

The July 2016 SDR indicates there are two dialysis facilities in Richmond County, both of which are owned and operated by Total Renal Care of North Carolina, LLC, as shown in the table below:

FACILITY	LOCATION	# STATIONS	# APPROVED STATIONS*	# PATIENTS	% UTILIZATION
Dialysis Care of Richmond County	Hamlet	27	3	86	79.63%
Sandhills Dialysis	Rockingham	16	0	58	90.63%

\*Stations approved but not yet certified  
Source: Table A, July 2016 SDR

Sandhills Dialysis was operating above capacity at 90.63% as of December 31, 2015. Dialysis Care of Richmond County was operating at 79.63%, with 3.185 patients per station per week. The average utilization of both DaVita dialysis facilities in Richmond County is 85.13%.

In Section N.1, page 48, the applicant states

*“The expansion of Sandhills Dialysis will have no effect on competition in Richmond County. Although the addition of stations at this facility could serve to provide more patients another option to select a provider that gives them the highest quality service and better meets their needs, this project primarily serves to address the needs of a population already served (or projected to be served based on historical growth rates) by Total Renal Care of North Carolina, LLC.*

*The expansion of Sandhills Dialysis will enhance accessibility to dialysis for our patients, and by reducing the economic and physical burdens on our patients, this project will enhance the quality and cost effectiveness of our services because it will make it easier for patients, family members, and other involved in the dialysis process to receive services.”*

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 Sandhills Dialysis will continue to provide quality services. The discussion regarding quality found in Criteria (1) and (20) is incorporated herein by reference.
- The applicant demonstrates that Sandhills Dialysis will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (1), (3) 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 49, the applicant describes the methods by which Sandhills Dialysis 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. In Exhibit O-2, the applicant provides documentation 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 – 14 the applicant demonstrates the need for six additional stations at Sandhills Dialysis based on 72 patients dialyzing on 22 in-center stations as of the end of the first operating year, which is 3.27 patients per station per week [ $72 / 22 = 3.27$ ;  $3.27 / 4 = 81.8\%$ ]. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

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

-C- In Section C.1, pages 13 – 14, 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.