

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: April 6, 2015

Findings Date: April 6, 2015

Project Analyst: Jane Rhoe-Jones

Team Leader: Lisa Pittman

Project ID #: H-011001-15

Facility: Sandhills Dialysis

FID #: 090624

County: Richmond

Applicant(s): Total Renal Care of NC, LLC

Project: Relocate four dialysis stations from Dialysis Care of Richmond County for a total of no more than 16 at Sandhills Dialysis 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.

C

Total Renal Care of North Carolina, LLC (TRC) d/b/a Sandhills Dialysis, whose parent company is DaVita HealthCare Partners, Inc., proposes to relocate four dialysis stations from Dialysis Care of Richmond County to the existing 12-station Sandhills Dialysis also in Richmond County, for a total of 16 dialysis stations at Sandhills Dialysis.

Need Determination

The applicant is relocating dialysis stations to an existing facility therefore, neither the county need nor facility need methodology in the 2015 State Medical Facilities Plan (SMFP) is applicable to this review.

Policies

Policy GEN-3: *Basic Principles* is not applicable because neither need methodology is applicable to the review and Policy GEN-4: *Energy Efficiency and Sustainability for Health Service Facilities* is not applicable because the capital expenditure of the proposed project is less than \$2.0 million.

However, Policy ESRD-2 is applicable to this review. Policy ESRD-2: *Relocation of Dialysis Stations* states:

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

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

The applicant proposes to relocate four dialysis stations within Richmond County, consequently, there is no change in the dialysis station inventory in Richmond County, and therefore the application is consistent with Policy ESRD-2.

Conclusion

The application is consistent with Policy ESRD-2 in the 2015 SMFP. Therefore, the application is conforming to this criterion.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic

minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

Total Renal Care of North Carolina, LLC d/b/a Sandhills Dialysis, whose parent company is DaVita HealthCare Partners, Inc., proposes to relocate four dialysis stations from Dialysis Care of Richmond County to Sandhills Dialysis, both located in Richmond County. Upon project completion, Sandhills Dialysis will have 16 dialysis stations. The January 2015 SMFP states that as of December 31, 2014, Sandhills Dialysis has 12 certified dialysis stations and Dialysis Care of Richmond County has 27 certified dialysis stations.

Population to be Served

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

“Richmond County has experienced a five year average annual change rate of 3.5%. While Sandhills Dialysis is not eligible to apply for an increase of dialysis stations since the facility utilization rate was 70.83% as published in the January 2015 SDR, the facility has experienced a census increase of 17 patients for the period from July 1, 2014 to December 31, 2014. On December 31, 2014 Sandhills had 51 in-center patients. This is a station utilization rate of 106.25%. The relocation of stations from Dialysis Care of Richmond County will help meet the growing demand for dialysis services at Sandhills Dialysis.”

In Section III.7, page 25, the applicant projects the number of patients to be served at Sandhills Dialysis during the first two years of operation following project completion as shown below:

SANDHILLS DIALYSIS						
Projected Dialysis Patient Origin						
COUNTY	OPERATING YEAR 1 2016		OPERATING YEAR 2 2017		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	IN-CENTER	HOME	IN-CENTER	HOME	YEAR 1	YEAR 2
Richmond	54	0	56	0	96.4%	96.6%
Other States	2	0	2	0	3.6%	3.4%
TOTAL	56	0	58	0	100.0%	100.0%

The applicant adequately identifies the population it proposes to serve.

Analysis of Need

In Section II, pages 15-16, and Section III.7, pages 25-26, the applicant provides the assumptions and methodology used to project the proposed in-center patient utilization of Sandhills Dialysis. The applicant states that Sandhills Dialysis had 34 in-center patients and 12 certified stations as of June 30, 2014, for a station utilization rate of 70.83%. However, as

of December 31, 2014, Sandhills Dialysis had 51 in-center patients utilizing 12 stations for a utilization rate of 106.25%, which is a 50.0% increase in utilization.

In Section III.3(d), page 23, the applicant states that dialysis is provided at only two locations in Richmond County, Sandhills Dialysis and Dialysis Care of Richmond County. The applicant is proposing to expand Sandhills Dialysis so that all in-center patients in the county can be accommodated without having to receive treatments on a third shift.

In Section I, page 3, the applicant projects that the 16 stations at Sandhills Dialysis (following relocation of four from Richmond County Dialysis) will be utilized at 87.5% of capacity by the end of the first year of operation (56 patients / (4 x 16) = .875). In Section II.1b, pages 16-17, the applicant provides assumptions to support projected utilization:

- There is a need for a minimum of one additional dialysis station in Richmond County; given that Table B of the January 2015 SDR indicates a one station deficit in the county.
- Sandhills Dialysis had a utilization rate of 70.83%; which did meet the 80% utilization rate required to apply for additional stations under the facility need methodology (January 2015 SDR).
- The applicant projects a 5% growth rate given the facility's increase of 17 in-center patients between July 1, 2014 and December 31, 2014. The January 2015 SDR indicates the five year average annual change rate (AACR) for Richmond County was 3.5%. Sandhills Dialysis has had an average annual change rate of 40% during the three years of operation.
- Meeting the requirements for Policy ESRD 2, TRC is proposing to transfer four stations from Dialysis Care of Richmond County to Sandhills Dialysis.
- Dialysis Care of Richmond County was issued a certificate of need to add three stations (Project ID# H-010271-14) for a total of 30 stations when the project is completed.
- Operating Year One is projected to begin January 1, 2016 and end on December 31, 2016.
- Operating Year Two is projected to begin January 1, 2017 and end on December 31, 2017.

A chart depicting the growth of Sandhills Dialysis is shown below:

SANDHILLS DIALYSIS		
Year	In-center Patients	Growth Rate
12/31/12	27	
12/31/13	30	11.1%
12/31/14	51	70.0%
3-year AACR		40.6%

On pages 16-17, the applicant provides the calculations used to project in-center dialysis patients at the Sandhills Dialysis facility:

*“January 1, 2015-December 31, 2015 - 49 patients x 1.05 = 51.450
January 1, 2016-December 31, 2016 - 51.450 patients x 1.05 = 54.0225
January 2, 2017-December 31, 2017 - 54.0225 patients x 1.05 = 56.723625*

...

The number of patients stated in the chart above was rounded down to the nearest whole number. No growth was calculated for the two in-center patients who lived out of state.

Sandhills Dialysis is projected to have 56 in-center patients at the end of operating year one for a utilization rate of 87.5% or 3.5 patients per station and 58 in-center patients at the end of operating year two for a utilization rate of 90.6% or 3.6 patients per station.”

Therefore, in Operating Year One, the applicant projects to serve 56 in-center patients on 16 dialysis stations, which is 3.5 patients per station, or 87.5% of capacity [$56 / 16 = 3.5$; $3.5 / 4 = 0.875$]. In Operating Year Two, the applicant projects to serve 58 in-center patients on 16 dialysis stations, which is 3.6 patients per station, or 90.6% of capacity [$58 / 16 = 3.62$; $3.6 / 4 = 0.906$]. Thus, in the first operating year, the applicant projects to serve at least 3.2 patients per station per day, as required by 10A NCAC 14C .2203(b).

Projected in-center utilization is based on reasonable and adequately supported assumptions regarding projected growth of dialysis patients at Sandhills Dialysis.

Access

In Section VI.1, pages 34-37, the applicant describes how underserved persons will have access to services provided by Sandhills Dialysis. On page 34, the applicant states:

“Sandhills Dialysis, 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, or handicap, or ethnic and socioeconomic groups of patients in need of dialysis regardless of their ability to pay.”

The applicant projects 84.3% of its patients will be covered by Medicare or Medicaid. The applicant adequately demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services.

Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for the 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.

C

The applicant proposes to relocate four stations from Dialysis Care of Richmond County to Sandhills Dialysis, currently a 12 station dialysis facility in Rockingham.

Dialysis Care of Richmond County

Dialysis Care of Richmond County is currently certified for 27 stations and will have 26 stations upon completion of this project (relocate four stations) and Project ID# H-10271-14 (add three stations).

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

“The January 2015 SDR indicated that Dialysis Care of Richmond County was treating 98 in-center patients as of June 30, 2014. The facility had 27 certified stations, with three stations pending development (CON Project H-10271-14). Dialysis Care of Richmond County is projected to certify these stations before the end of 2015. With the transfer of four stations to Sandhills Dialysis, this will leave Dialysis Care of Richmond County with 26 certified stations. This certificate of need application does not call for the transfer of any patients from Dialysis Care of Richmond County to Sandhills Dialysis.

The January 2015 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 Dialysis Care of Richmond County for the period July 1, 2014 through December 31, 2017, the proposed end of operating year two for the Sandhills Dialysis expansion.

July 1, 2014-December 31, 2014 - 98 patients X 1.0175 = 99.715

January 1, 2015-December 31, 2015 - 99.715 patients X 1.035 = 103.205025

January 1, 2016-December 31, 2016 - 103.205025 patients X 1.035 = 106.8172008

January 1, 2017-December 31, 2017 - 106.8172008 patients X 1.035 = 110.5558028

Based on the information above, the Dialysis Care of Richmond County would have 106 in-center patients at the end of operating year one for a utilization rate of 101.9% or 4.1 patients per station and 110 in-center patients at the end of operating year two for a utilization rate of 105% or 4.2 patients per station. However, Dialysis Care of Richmond County will apply for an additional two dialysis stations on March 16,

2015. The additional of these two stations will adjust the utilization rates for operating years one and two. The additional stations will give the facility 28 in-center stations. The utilization rate for operating year one will be 94.6% or 3.8 patients per station based on 28 certified dialysis stations. The utilization rate for operating year two will be 98.2% or 3.9 patients per station based on 28 certified dialysis stations. The proposed four station expansion of the Sandhills Dialysis Center and the two-station expansion of Dialysis Care of Richmond County will be certified on the same date. Therefore, the patients at Dialysis Care of Richmond County will have an adequate number of stations available. If Dialysis Care of Richmond County experiences a more aggressive growth, Total Renal Care of North Carolina will submit additional certificate of need applications to increase the number of stations utilizing the facility need methodology.”

Conclusion

The applicant demonstrates that the needs of the population presently served at Dialysis Care of Richmond County; including underserved groups, will be adequately met following relocation of four stations to Sandhills Dialysis. 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.

C

In Section III.9, pages 26-27, the applicant states the two alternatives considered to meet the needs for the proposed project.

The alternative that the applicant considered and decided as not being the least costly or most effective alternatives is:

- Maintain status quo: The applicant states that the patient population continues to grow and that there is a one-station deficit in Richmond County.

The alternative that the applicant considered and decided is the least costly or most effective alternatives is:

- Apply for the four station expansion by relocating stations within the host county from Dialysis Care of Richmond County. The applicant states that this alternative will help meet the growing demand for dialysis services at Sandhills Dialysis.

On pages 26-27, the applicant describes the cost effective approaches utilized in its facilities.

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 the proposal is the least costly or most effective alternative to meet the need for relocating four dialysis stations from Dialysis Care of Richmond County to Sandhills Dialysis, both located in Richmond County. 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 develop no more than four additional dialysis stations and operate no more than sixteen dialysis stations at Sandhills Dialysis which shall include any home hemodialysis training or isolation stations.**
 - 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 four additional dialysis stations which shall include any home hemodialysis training or isolation stations.**
 - 4. After certification of the four relocated dialysis stations at Sandhills Dialysis, Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Richmond County shall take steps to decertify four dialysis stations for a total of no more than 26 certified stations at Dialysis Care of Richmond County upon completion of this project (relocate four stations), and Project ID# H-10271-14 (add three stations).**
 - 5. 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

In Section VIII.1, pages 42-44, the applicant states that the total capital cost of the project will be \$67,016 which includes \$50,000 for dialysis machines, \$4,540 for dialysis chairs, \$6,000 for televisions, \$3,276 for computers, and \$3,200 for other equipment.

In Section IX.3, page 47, the applicant projects no working capital (start-up and initial operating expenses) associated with the proposed project as Sandhills Dialysis is an existing operating facility.

In Section VIII.2, page 44, the applicant states that the project will be funded from cash reserves of DaVita HealthCare Partners, Inc., the parent company of Total Renal Care of North Carolina, LLC.

Exhibit 18 contains a letter dated February 11, 2015 from the Chief Accounting Officer of DaVita HealthCare Partners, which states:

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

... This letter will confirm that DaVita HealthCare Partners, Inc. has committed cash reserves in the total sum of \$67,016, 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.”

Exhibit 19 contains the audited financial statements for DaVita HealthCare Partners, Inc. for the fiscal year ended December 31, 2013. As of December 31, 2013, DaVita had \$946,249,000 in cash and cash equivalents, \$17,098,877,000 in total assets and \$5,302,841,000 in net assets [total assets (\$17,098,877,000) less total liabilities (\$11,796,036,000)]. The applicant adequately demonstrates the availability of funds for the capital needs of the project.

In Section X.1, page 49, the applicant provides the allowable charges per treatment for each payment source for Sandhills Dialysis, as illustrated below in the table.

SANDHILLS DIALYSIS	
Payor	Charge Per Treatment
Medicare	\$239.43
Medicaid	\$143.00
Medicare/Medicaid	\$239.43
Commercial Insurance	\$1,275.00
VA	\$193.00
Medicare/Commercial	\$239.43

The applicant projects revenues in Section X.2, page 50 and X.4, page 53, and operating expenses in Section X.4, page 53. In Section X.2 and X.4, pages 50 and 53, the applicant reports projected revenues and expenses for Sandhills Dialysis, as illustrated below in the table:

SANDHILLS DIALYSIS		
	Operating Year 1	Operating Year 2
Total Net Revenue	\$3,139,780	\$3,283,787
Total Operating Costs	\$2,304,876	\$2,398,982
Net Profit	\$834,904	\$884,805

The applicant projects that revenues will exceed operating expenses in each of the first two operating years following projection completion. The assumptions used in preparation of the pro formas, including the number of projected treatments are reasonable and adequately supported. In Section VII.1, page 38 and Section X.5, page 54, the applicant provides projected staffing and salaries. See Section X of the application for the applicant’s assumptions. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

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.

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Total Renal Care of North Carolina, LLC (TRC) d/b/a Sandhills Dialysis, proposes to relocate four dialysis stations from Dialysis Care of Richmond County to the existing 12-station Sandhills Dialysis also in Richmond County for a total of 16 dialysis stations at Sandhills Dialysis.

There are two existing dialysis facilities located in Richmond County; Sandhills Dialysis in Rockingham and Dialysis Care of Richmond County in Hamlet. Both facilities are owned by the applicant or a related entity.

The following table identifies the existing dialysis facilities located in Richmond County as reported in Table A of the January 2015 SDR.

Facility	Existing	Approved /Relocate as of 6/30/14	# of In-center patients	Utilization Rate as of 6/30/14
Sandhills Dialysis	12	NA	34	70.83%
Dialysis Care of Richmond County	27	+3/-4	98	90.74%

Source: January 2014 SDR. *¹<http://www.mapquest.com>

As shown in the table above, Sandhills Dialysis has a utilization rate above 70%; while the utilization rate at Dialysis Care of Richmond County is above 90%. The two facilities in Richmond County are within ten miles of each other and less than 15 minutes travel time.

The relocation of existing stations from Dialysis Care of Richmond County to Sandhills Dialysis will not change the inventory of certified stations within Richmond County.

Consequently, 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. Therefore, 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 38, the applicant provides projected staffing for Sandhills Dialysis, as illustrated in the following table:

SANDHILLS DIALYSIS			
Full-Time Equivalent (FTE) Positions			
	Current	Add	Total
RN	2.0	0	2.0
PCT	5.0	1.0	6.0
Bio-Med Tech	0.5	0	0.5
Admin.	1.0	0	1.0
Dietician	0.5	0	0.5
Social Worker	0.5	0	0.5
Unit Secretary	1.0	0	1.0
Reuse	1.0	0	1.0
Total FTEs	11.5	1.0	12.5

The applicant projects a total of 12.5 FTE positions upon project completion. The applicant also states it expects no difficulty in recruiting staff for the additional position. In Section V.4, page 32 and Section VII.2, page 39, the applicant identifies the Medical Director for Sandhills Dialysis as Dr. Jennifer Stoddard. In Exhibit 13, the applicant provides a letter from Dr. Stoddard indicating her support for the project as a Nephrologist and as the Medical Director of the facility. Additionally, in Section VII.10, page 41, the applicant states Sandhills Dialysis will operate two shifts, six days a week from 6:00 a.m. to 4:00 p.m.

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 Section V.1, page 30, the applicant lists the providers of the necessary ancillary and support services. Exhibits 9 and 10 contain documentation on service agreements. The applicant adequately demonstrates that necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing healthcare system. Therefore, the application is conforming to this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (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(b), page 34, the applicant reports the payor mix for Sandhills Dialysis. The applicant reports that 84.3% of the in-center patients who received treatments at Sandhills Dialysis had some or all of their services paid for by Medicare or Medicaid in the past year. The table below illustrates the historical payment source for this existing facility:

SANDHILLS DIALYSIS 2014 IN-CENTER PAYOR MIX	
PAYOR	PERCENTAGE
Medicare	27.45%
Medicaid	0%
Medicare/ Medicaid	29.41%
Commercial Insurance	15.69%
VA	0%
Medicare/Commercial	27.45%
Total	100.00%

The Division of Medical Assistance (DMA) maintains a website which provides the number of persons eligible for Medicaid in North Carolina, and estimates the percentage of uninsured people for each county. The following table illustrates those percentages for Richmond County and statewide.

COUNTY	2010 Total # of Medicaid Eligibles as % of Total Population *	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *
Richmond	27.9%	12.4%	21.4%
Statewide	16.5%	6.7%	19.7%

*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 services offered by dialysis facilities. In fact, in 2013 only 6.6% of all newly-diagnosed ESRD patients in North Carolina were under the age of 35, according to the ESRD Network 6 2013 Annual Report. (*ESRD Network 6 2013 Annual Report/Data Table 1: ESRD Incidence – One Year Statistics as of 1/1/2013 – 12/21/2013, page 99*).¹

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina, as well as data sorted 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 do not include information on the number of elderly, handicapped, minorities or women utilizing health services.

Additionally, The United States Renal Data System, in its *2013 USRDS Annual Data Report*, pages 216-223, provides national statistics for FY 2011:

*“The December 31, 2011 prevalent population included 430,273 patients on dialysis ...”*² (p. 216)

The report also provides the incidence of dialysis patients in 2011, adjusted by age, gender and race, which show that 65.4% were white, 28.0% were African American, 15.0% were Hispanic, 4.7% were Asian, and 1.2% were Native American. (p.216) Moreover, the prevalence of ESRD for the 65-74 year old population grew by 31% since 2000 and by 48% for those aged 75 and older (p. 216). The report further states:

“In the 2011 prevalent population, 84 percent of hemodialysis patients and 81 percent of those on peritoneal dialysis had some type of primary Medicare coverage, compared to just 53 percent of those with a transplant.” (p. 216)

The *2013 USRDS Annual Data Report* provides 2011 ESRD spending by payor, as follows:

ESRD Spending by Payor		
Payor	Spending in Billions	% of Total Spending
Medicare Paid	\$30.7	62.4%
Medicare Patient Obligation	\$4.7	9.6%
Medicare HMO	\$3.6	7.3%
Non-Medicare	\$10.2	20.7%
Total	\$49.2	100.0%

¹ <http://www.esrdnetwork6.org/utills/pdf/annual-report/2013%20Network%206%20Annual%20Report.pdf>

² www.usrds.org/adr.aspx

The Southeastern Kidney Council (SKC) Network 6 2013 Annual Report provides prevalence data on North Carolina ESRD patients by age, race and gender on page 101, summarized as follows:

Number and Percent of Dialysis Patients by Age, Race, and Gender 2013		
	# of ESRD Patients	% of Dialysis Population
Age		
0-19	65	0.4%
20-34	766	5.0%
35-44	1,498	9.7%
45-54	2,746	17.8%
55-64	4,039	26.2%
65+	6,275	40.8%
Gender		
Female	6,845	44.5%
Male	8,544	55.5%
Race		
African-American	9,559	62.1%
White/Caucasian	5,447	35.4%
Other	383	2.5%

Source: SKC Network 6. Table includes North Carolina statistics only.³

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 applicant;

C

In Section VI.1(f), page 35, 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 Sandhills Dialysis has no obligation under the Hill Burton Act.”

³<http://www.esrdnetwork6.org/utills/pdf/annual-report/2013%20Network%206%20Annual%20Report.pdf>

In Section VI.6(a), page 37, the applicant states, “*There have been no civil rights equal access complaints filed within the last five years.*”

Therefore, 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 35, the applicant provides the projected payor mix for the proposed in-center services and it is the same as the applicant’s current payor mix depicted in Criterion (13)(a). The applicant projects that 84.3% of in-center patients at Sandhills Dialysis will have their services paid for by Medicare and Medicaid.

SANDHILLS DIALYSIS 2014 IN-CENTER PAYOR MIX	
PAYOR	PERCENTAGE
Medicare	27.45%
Medicaid	0%
Medicare/ Medicaid	29.41%
Commercial Insurance	15.69%
VA	0%
Medicare/Commercial	27.45%
Total	100.00%

In Section VI.1(a), page 34, the applicant states,

“Sandhills Dialysis does not require payment upon admission to its services; therefore, services are available to all patients including low-income persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served persons.”

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 VI.5, page 36, the applicant states:

*“Patients with End Stage Renal Disease have access to dialysis services upon referral to a Nephrologist with privileges at Sandhills Dialysis. Patients, families and friends can obtain access by contacting a Nephrologist with privileges at the facility. Should a patient contact Sandhills Dialysis directly or indirectly, the patient is referred to a qualified Nephrologist for evaluation and subsequent admission if medically necessary. Patients from outside the Sandhills Dialysis catchment area requesting transfer to this facility are processed in accordance with the Sandhills Dialysis transfer and transient policies which comprise **Exhibit 14**. [Emphasis in original.] The patient, again, is referred to a qualified Nephrologist for evaluation and subsequent admission if medically necessary.”*

The applicant adequately demonstrates that it will provide a range of means by which a person can access 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 V.3, page 32, the applicant states that the TRC legal department and the Chair of the Allied Health Department at Richmond Community College are working to establish a training agreement for student nurses. See Exhibit 12 for documentation.

The information provided in Section V.3 is reasonable and credible for an existing operating facility and supports a finding of conformity 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 (TRC) d/b/a Sandhills Dialysis proposes to relocate four dialysis stations from Dialysis Care of Richmond County to the existing 12-station Sandhills Dialysis also in Richmond County, for a total of 16 dialysis stations at Sandhills Dialysis.

The applicant or a related entity owns both dialysis facilities in Richmond County. In Section V.7, page 33, the applicant discusses how the project will promote cost effectiveness, quality and access to the proposed services in the service area. The applicant states:

“The proposed expansion of the facility is an effort to provide dialysis services to this community and is not intended to be a competitive venture. ... patient selection is the determining factor, as the patient will select the provider that ... best meets their needs. Sandhills Dialysis provides access to all qualified Nephrologists to admit his or her patients.”

See also Sections II (pages 14-20), III (pages 22-24, and 26-27), V (pages 30-33), VI (pages 34-37), VII (pages 38-41) and referenced exhibits, where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicant in the above sections is reasonable and credible and adequately demonstrates that the proposed project would have a positive impact on cost-effectiveness, quality and access to the proposed services. This determination is based on 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 it will continue to provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicant demonstrates that it will continue to provide adequate access to medically underserved populations. The discussion regarding access found in Criterion (13) is incorporated herein by reference.

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.

The applicant currently provides dialysis services at Sandhills Dialysis and Dialysis Care of Richmond County and is proposing to relocate dialysis stations from Dialysis Care of Richmond County to expand services at Sandhills Dialysis. According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, Sandhills Dialysis and Dialysis Care of Richmond County operated in compliance with the Medicare Conditions of Participation 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, as promulgated in 10A NCAC 14C Section .2200, are applicable to this review. The proposal is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C Section .2200. The specific findings are discussed below.

SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES

.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 Section III.7, page 25, the applicant states that the utilization rates at Sandhills Dialysis are reported in the January 2015 SDR, which is provided as Exhibit 7. The June 30, 2014 SDR utilization rate of 70.8% was calculated based on 34 in-center patients on 12 dialysis stations (34 patients / 12 stations = 2.8 patients per station; 2.8 patients per station / 4.00 patients per station = .708). The December 2014 utilization rate of 106% was calculated based on 51 in-center dialysis patients and 12 certified dialysis stations as of December 31, 2014 (51 patients / 12 stations = 4.25 patients per station; 4.25 patients per station / 4.00 patients per station = .106).

- (2) *Mortality rates;*

- C- In Section IV.2, page 28, the applicant reports the following for Sandhills Dialysis:
- | | |
|------|-------|
| 2012 | 14.8% |
| 2013 | 14.0% |
| 2014 | 4.9% |
- (3) *The number of patients that are home trained and the number of patients on home dialysis;*
- C- In Section IV.3, page 28, the applicant states that based on an agreement between the two facilities, Dialysis Care of Moore County provides home training for Sandhills Dialysis patients. See Exhibit 11 for a copy of the agreement.
- (4) *The number of transplants performed or referred;*
- C- In Section IV.4, page 28, the applicant states, “*Sandhills Dialysis referred 5 patients for a transplant evaluation in 2014. Sandhills Dialysis had zero patients receive transplants in 2014.*”
- (5) *The number of patients currently on the transplant waiting list;*
- C- In Section IV.5, page 29, the applicant states, “*Sandhills Dialysis has 4 patients 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 29, the applicant states that Sandhills Dialysis had 95 patients admitted to the hospital in 2014, nine (9.4%) of which were dialysis related and 86 (90.5%) 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 29, the applicant states that there were two patients dialyzing at Sandhills Dialysis with AIDS, two patients with Hepatitis B, and there were no patients who converted to infectious status within the last year.
- (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- Sandhills Dialysis is not a new facility.

- (2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*
- (A) *timeframe for initial assessment and evaluation of patients for transplantation,*
 - (B) *composition of the assessment/evaluation team at the transplant center,*
 - (C) *method for periodic re-evaluation,*
 - (D) *criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and*
 - (E) *signatures of the duly authorized persons representing the facilities and the agency providing the services.*

-NA- Sandhills Dialysis is not a new facility.

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

-NA- Sandhills Dialysis is not a new facility.

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

-NA- Sandhills Dialysis is not a new facility.

- (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- Sandhills Dialysis is not a new 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- See Section XI.6(g), page 59. See also Exhibit 22 regarding water quality, Exhibit 23 for excerpts from the applicant’s Health and Safety Policy and Procedure Manual, and Exhibit 24 for the In-Service Calendar with mandatory training classes.

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

-C- The applicant provides projected patient origin in Section III.7, page 25, which is reproduced in the following table:

SANDHILLS DIALYSIS						
Projected Dialysis Patient Origin						
COUNTY	OPERATING YEAR 1 2016		OPERATING YEAR 2 2017		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	IN-CENTER	HOME	IN-CENTER	HOME	YEAR 1	YEAR 2
Richmond	54	0	56	0	96.4%	96.6%
Other States	2	0	2	0	3.6%	3.4%
TOTAL	56	0	58	0	100.0%	100.0%

See Section III.7, pages 24-26, for the applicant’s methodology and assumptions used to project patient origin. The discussion regarding population to be served 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- Sandhills Dialysis is not a new 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(9), page 14, the applicant states, “*Total Renal Care of North Carolina d/b/a Sandhills Dialysis will admit and provide dialysis services to patients who have no insurance or other source of payment, if payment for dialysis services is made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.*”

.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- Sandhills Dialysis is not a new 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- In Section II.1, page 15, Sandhills Dialysis projects utilization of 3.5 patients per station per week as of the end of the first operating year. The discussion regarding analysis of 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.*

The applicant provides all assumptions, including the methodology by which patient utilization is projected in Sections II and III. The discussion regarding utilization found in Criterion (3) is incorporated herein by reference.

.2204 SCOPE OF SERVICES

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

- (1) *diagnostic and evaluation services;*
- C- The table in Section V.1, page 30, states patients are referred to Richmond Memorial Hospital for diagnostic and evaluation services.
- (2) *maintenance dialysis;*
- C- The table in Section V.1, page 30, states the applicant provides in-center maintenance dialysis.
- (3) *accessible self-care training;*
- C- The table in Section V.1, page 30, states that Dialysis Care of Moore County provides in-center hemodialysis self-care training, intermittent peritoneal dialysis, CAPD and CCPD.
- (4) *accessible follow-up program for support of patients dialyzing at home;*
- C- The applicant addresses the accessible follow-up program for support of patients dialyzing at home in Section V.2(d), page 31.

(5) *x-ray services;*

-C- The table in Section V.1, page 30, states patients are referred to Richmond Memorial Hospital for x-ray services.

(6) *laboratory services;*

-C- The table in Section V.1, page 30, states patients are referred to Dialysis Laboratories for routine, special and immunological laboratory services.

(7) *blood bank services;*

-C- The table in Section V.1, page 30, states patients are referred to Richmond Memorial Hospital for blood bank services.

(8) *emergency care;*

-C- The table in Section V.1, page 30, states patients are referred to Richmond Memorial Hospital for emergency care.

(9) *acute dialysis in an acute care setting;*

-C- The table in Section V.1, page 30, states patients are referred to Richmond Memorial Hospital for acute dialysis in an acute care setting.

(10) *vascular surgery for dialysis treatment patients;*

-C- The table in Section V.1, page 30, states dialysis patients are referred to Richmond Memorial Hospital for vascular surgery.

(11) *transplantation services;*

-C- The table in Section V.1, page 30, states patients are referred to Duke University Medical Center. See Exhibit 10 for documentation from Duke University Medical Center.

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

-C- The table in Section V.1, page 30, states patients are referred to the North Carolina Division of Vocational Rehabilitation Services for vocational rehabilitation counseling and services.

(13) *transportation.*

-C- The table in Section V.1, page 30, states patients are referred to ART Transit.

.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 [sic].*

-C- In Section VII.1, page 38, the applicant provides the proposed staffing for Sandhills Dialysis. The applicant states, *“The facility complies with all staffing requirements as stated in 42 C.F.R. Section 405.2100 [sic] ...”* 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 Section VII.5, page 39, the applicant refers to Exhibit 17 for a copy of the training program description/outline which is DaVita’s *“Training Programs for New Patient Care Provider Teammates.”* Exhibit 24 contains the *Annual In-Service Calendar* for Sandhills Dialysis.