

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: June 27, 2014

PROJECT ANALYST: Gregory F. Yakaboski

INTERIM CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: H-10271-14/ Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Richmond County/ Add three dialysis station for a total of 30 certified dialysis stations/ Richmond County

### 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.

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Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Richmond County (DC of Richmond County) proposes to add three dialysis station for a total of 30 certified dialysis stations upon completion of this project.

According to the January 2014 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of two dialysis stations in Richmond County. However, the applicant is eligible to apply for additional stations in its existing facility based on application of the facility need methodology because the utilization rate reported for DC of Richmond County in the January 2014 SDR is 3.4074 patients per station. This utilization rate was calculated based on 92 in-center dialysis patients and 27 certified dialysis stations (92 patients / 27 stations = 3.4074 patients per station).

Application of the facility need methodology indicates additional stations are needed for this facility, as illustrated in the following table.

Required SDR Utilization		80%
Center Utilization Rate as of 6/30/13		85.2%
Certified Stations		27
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>27</b>
In-Center Patients as of 6/30/13 (SDR2)		92
In-Center Patients as of 12/31/12 (SDR1)		85
Step	Description	
(i)	Difference (SDR2 - SDR1)	7
	Multiply the difference by 2 for the projected net in-center change	14
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/12	0.1647
(ii)	Divide the result of Step (i) by 12	0.0137
(iii)	Multiply the result of Step (ii) by 6 (the number of months from 6/30/13 until 12/31/13)	0.0824
(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	99.5765
(v)	Divide the result of Step (iv) by 3.2 patients per station	31.1176
	and subtract the number of certified and pending stations as recorded in SDR2 [27] to determine the number of stations needed	4

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is 4 stations. 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 three new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policy GEN-3: Basic Principles, page 38 of the 2014 State Medical Facilities Plan (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.”*

### **Promote Safety and Quality**

In Section II.3, pages 16-17, the applicant discusses the quality of services provided at DaVita HealthCare Partners, Inc. owned and operated ESRD facilities. The applicant states that its success in providing quality services stems from a comprehensive Quality Management Program that includes the following components:

- *“Quality Improvement Methodology – utilizing outcome-driven, patient centered management programs to measure, monitor and manage outcomes.*
- *Computerized Information System – integrating clinical and laboratory information for comprehensive outcomes tracking and reporting.*
- *Staff and Patient Education Program – ensuring continuous updates and training to ensure high quality patient care.*
- *Quality Assessment Audit Program – systematically utilizing a comprehensive detailed assessment tool to assure the highest quality standards in every facility.*
- *Quality Management Team – experienced clinical facilitators to implement and maintain ongoing quality improvement programs.*
- *Quality Biomedical Team – experienced specialists in all aspects of Biomedical requirements (i.e., water treatment, reuse, disinfection and machine maintenance).”*

The applicant further states on page 17, that the company’s goal is to have each facility serve as a quality improvement laboratory where successful outcomes can be disseminated throughout DaVita. Exhibit 22 contains the DaVita’s Health and Safety Policy & Procedure Manual which includes a section on General Health and Safety Policies. The Health and Safety Policies state, in part:

*“The Health and Safety Policy & Procedure Manual is designed to ensure compliance and provide policy and procedure for teammate health and safety issues. Using this manual, each DaVita facility will meet Federal regulations as they relate to Risk and Occupational Safety Health and Administration (OSHA), support the corporate philosophy of consistent practice and operations of facilities within the company ...”*

The applicant adequately demonstrates that the proposal will promote safety and quality care at DC of Richmond County.

### **Promote Equitable Access**

In Section VI., pages 29-31, the applicant states that DC of Richmond County has and will continue to provide services to all residents of the service area without regard to race, sex, age, gender, handicap, ethnic or socioeconomic groups in need of dialysis service regardless of their ability to pay. The applicant further states on page 29 that 92.0% of its patients had some or all of their services paid for by Medicare or Medicaid.

The applicant adequately demonstrates that the proposal will promote equitable access.

### **Maximize Healthcare Value**

In Section III.9, pages 21-22, the applicant states that DC of Richmond County will maximize healthcare value in several ways which include utilization of a centralized purchasing department to negotiate national contracts with numerous vendors in order to secure the best product available at the best price; utilization of the reuse process that contains costs and the amount of dialyzer waste generated by the facility; the use of an electronic patient charting system that reduces the need for paper in the facility; preventative maintenance on the dialysis machines on a monthly, quarterly and semi-annual schedule to reduce the need for repairs of the dialysis equipment; and an inventory control plan that ensures enough supplies are available without having an inordinate amount of supplies on hand.

The applicant adequately demonstrates that the proposal will maximize healthcare value.

The applicant adequately demonstrates the proposal will incorporate the basic principles of Policy GEN 3. The application is also consistent with the facility need determination in the 2014 SMFP and is therefore 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.

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DC of Richmond County proposes to add three dialysis station for a total of 30 certified dialysis stations upon completion of this project.

Population to be Served

In Section IV.1, page 23, the applicant identifies the population served, as of June 30, 2013, as illustrated in the table below.

County of Residence	# of Patients Dialyzing In-center	Home Patients	Dialysis
Richmond	79	5	
Scotland	6	2	
Anson	1	0	
Robeson	0	2	
South Carolina	6	1	
Total	92	10	

In Section III.7, page 20, the applicant identifies the patient population it proposes to serve during the first two years of operation following project completion, as illustrated in the table below:

**Projected Dialysis Patient Origin**

COUNTY	Operating Year 1 2015		Operating Year 2 2016		County Patients as a Percent of Total	
	In-Center Patients	Home Dialysis Patients	In Center Patients	Home Dialysis Patients	Year 1	Year 2
Richmond	83	5	86	5	83.1%	83.6%
Anson	1	0	1	0	0.9%	0.9%
Scotland	6	2	6	2	7.5%	7.3%
Robeson	0	2	0	2	1.9%	1.8%
South Carolina	6	1	6	1	6.6%	6.4%
TOTAL	96	10	99	10	100%	100%

The applicant adequately identified the population it proposes to serve.

**Need Analysis**

In Section III.7, pages 20-21, the applicant provides the following assumptions for the proposed project:

Operating Year One is January 1, 2015 – December 31, 2015

Operating Year Two is January 1, 2016 – December 31, 2016

The number of patients stated in the calculations below were rounded down to the nearest whole number.

As of June 30, 2013, DC of Richmond County had 92 in-center patients: 79 from Richmond County.

The Average Annual Change Rate for Richmond County over the past five years is 3.0% (See Table B, January 2014 SDR).

The applicant did not grow the in-center patients living outside of Richmond County who currently receive treatment at DC of Richmond County.

Table A of the January 2014 SDR states that as of June 30, 2013, DC of Richmond County had a utilization rate of 85.19% or 3.4074 patients per station based on 92 in-center patients and 27 certified stations.

The applicant calculated growth starting on January 1, 2014 with 79 patients from Richmond County. The applicant did not grow the 13 in-center patients from outside Richmond County who utilized DC of Richmond County as of June 30, 2013. The 13 in-center patients from outside Richmond County were added back in after growth of the 79 in-center patients from Richmond County was calculated. The projected utilization calculations are set forth below:

*“January 1, 2014 – December 31, 2014 -79 patients X 1.03 = 81.37*

*January 1, 2015 – December 31, 2015 – 81.37 patients X 1.03 = 83.8111.*

*January 1, 2016 – December 31, 2016 – 83.8111 patients X 1.03 = 86.325.”*

By the end of Year One, the applicant projects to serve 96 in-center patients (83 from Richmond County and 13 in-center patients living outside of Richmond County) dialyzing on 30 stations for a utilization rate of 80.0% or 3.2 patients per station [ $96 / 30 = 3.2 / 4.0 = 0.8$  or 80.0%]. The applicant projects 99 in-center patients (86 from Richmond County and 13 in-center patients living outside of Richmond County) at the end of Year Two for a utilization rate of 82.5% or 3.3 patients per station [ $99 / 30 = 3.3 / 4.0 = 0.825$  or 82.5%]. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year required by 10A NCAC 14C .2203(b). As of December 31, 2013, DC of Richmond County was serving 93 in-center patients; 82 from Richmond County. Based on the data reported to DHSR by DC of Richmond County for the July 2014 SDR. Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

### **Access to Services**

In Section VI, page 29, the applicant states:

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

...

*DC of Richmond County 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. DC of Richmond County works with patients who need transportation, when necessary.”*

The applicant projects that 61.3% of its patients will have all or part of their services covered by Medicare and or Medicaid, 3.0% will be covered by VA and another 30.7% will be covered by Medicare/Commercial. The applicant adequately demonstrates 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.

In summary, the applicant adequately identifies the population to be served, demonstrates the need that population has for the proposed project and the extent to which all residents of the area are likely to have access to the services proposed. Therefore, the application is conforming to this criterion.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

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- (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.

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In Section III.9, page 21, the applicant discusses the alternatives considered by DC of Richmond County, which include:

1. Maintain the Status Quo –the applicant dismissed this alternative based on the fact that with the continued growth at the facility there is a need. Therefore, doing nothing would not be in the best interest of their patients.
2. Add three stations – the applicant concluded that the proposal to add three additional dialysis stations was its most effective alternative to meet the fast growing need for dialysis services at the DC of Richmond County facility. Thus, the applicant concluded that the project as proposed was its least costly and most effective alternative.

The applicant adequately demonstrates the need for three additional stations based on the facility's projected utilization. See Criterion (3) for discussion on need which is incorporated hereby as if set forth fully herein.

The application is conforming to all other applicable statutory and regulatory review criteria, and thus is approvable. An application that cannot be approved cannot be an effective alternative.

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

- 1. Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Richmond County shall materially comply with all representations made in the certificate of need application.**
- 2. Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Richmond County shall develop no more than three additional stations for a total of no more than 30 stations upon completion of this project, which shall include any home hemodialysis training or isolation stations.**
- 3. Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Richmond County shall install plumbing and electrical wiring through the walls for no more than three additional dialysis stations for a total of no more than 30 dialysis stations, which shall include any home hemodialysis training or isolation stations.**
- 4. Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Richmond County shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**



- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

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In Sections VIII, page 38, the applicant projects the total capital cost for the project will be \$53,876, including \$40,500 for dialysis machines, \$3,795 for equipment/furniture, \$2,925 for dialysis chairs, \$4,500 for televisions and 2,156 for chairside computers.

In Section IX, page 42, the applicant projects no initial start-up costs or initial operating expenses.

In Section VIII, pages 38-40, the applicant states it will fund the capital needs of the proposed project from the cash reserves of DaVita HealthCare Partners, Inc., the parent company of Total Renal Care, Inc. and Total Renal Care of North Carolina, LLC. Exhibit 17 contains a letter, dated March 3, 2014, from the Chief Accounting Officer of DaVita HealthCare Partners, Inc, which states:

*“I am the Chief Accounting Officer of DaVita HealthCare Partners, Inc., the parent and 100% owner of DVA Healthcare Renal Care, Inc. I also serve as the Chief Accounting Officer of Total Renal Care, Inc. which owns 85% of the ownership interests in Total Renal Care of North Carolina, LLC.*

*We are submitting a Certificate of Need Application to expand our DC of Richmond County by three ESRD stations. The project calls for a capital expenditure of \$53,876. This letter will confirm that DaVita HealthCare Partners, Inc. has committed cash reserves in the total sum of \$53,876. for the project capital expenditure. DaVita HealthCare Partners, Inc. will make these funds, along with any other funds that are necessary for the development of the project, available to Total Renal Care of North Carolina.”*

In Exhibit 18, the applicant provides the United States Securities and Exchange Commission Form 10-K for the Fiscal Year ending December 31, 2013 for DaVita Healthcare Partners, Inc. As of December 31, 2013, DaVita Healthcare Partners, Inc. had \$946,249,000 in cash and cash equivalents, \$17,098,877 in total assets and \$5,302,841 in net assets. (See page F-6 of Exhibit 18) The applicant adequately demonstrates the availability of funds for the capital needs of the project.

In Section X.1, page 44, the applicant provides the allowable charges per treatment for each payment source for DC of Richmond County, as illustrated in the table below:

Payor	Allowable Charge Per In-center Treatment
Medicare	\$240.00
Medicaid	\$143.00
Medicare/Medicaid	\$240.00
Commercial Insurance	\$1,175.00
VA	\$193.00
Medicare/Commercial	\$240.00

In Sections X.2-X.4, pages 44-46, the applicant projects revenues and operating expenses for DC of Richmond County, as illustrated in the table below:

	Operating Year 1	Operating Year 2
Total Net Revenue	\$4,202,870	\$4,303,483
Total Operating Costs	\$3,673,877	\$3,768,881
<b>Net Profit</b>	<b>\$528,993</b>	<b>\$534,602</b>

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. The assumptions used in preparation of the pro formas, including the number of projected treatments, are reasonable, credible and adequately supported. See Section X, pages 44-47, for the applicant's assumptions.

The applicant adequately demonstrated that the financial feasibility of the proposal is based on reasonable and supported projections regarding revenues and operating expenses. Therefore, the application is conforming to this criterion.

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

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The applicant proposes to add three dialysis stations to its existing facility for a total of 30 certified dialysis stations upon completion of the proposed project. According to the January 2014 SDR, the county need methodology shows there is a surplus of two dialysis stations in Richmond County. Although the January 2014 SDR shows there is a surplus of two dialysis stations in Richmond County, in this application, the applicant is applying for additional stations based on the facility need methodology. According to the January 2014 SDR, DC of Richmond County is one of two existing dialysis facilities in Richmond County owned by the same parent. The applicant adequately demonstrates the need for three additional stations based on the number of in-center patients it

currently serves and proposes to serve. The growth projections are based on Richmond County's projected five-year average annual growth rate in the number of dialysis patients. As of June 30, 2013, the 27-station DC of Richmond County facility was operating at 85.19% capacity ( $92 / 27 = 3.4074 / 4 = 0.85.185$  or 85.19 %). The target utilization rate is 80% or 3.2 patients per station per week as of the end of the first operating year of the facility. The facility will have 30 stations and is projected to serve 96 in-center patients by the end of Year One, which is a utilization rate of 80.0% or 3.2 patients per station [ $96 / 30 = 3.2 / 4.0 = 0.8$  or 80.0%]. As of December 31, 2013, the facility was already serving 93 in-center patients on 27 stations, which is a utilization rate of 86.1% ( $93/27=3.44$ ;  $3.44/4 = 0.861$ ).

The other facility in Richmond County is certified for 12 stations and is currently serving 30 in-center patients, which is a utilization rate of 62.5% ( $30/12= 2.5$ ;  $2.5/4 = 0.625$ ). This facility has only been in existence since September 2012.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Consequently, the application is conforming to this criterion.

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

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In Section VII.1, page 33, the applicant states that DC of Richmond County currently employs 22.2 full-time equivalent (FTE) positions. The applicant does not propose to hire additional staff as a result of the proposed project. The applicant further states on page 33, *"The facility complies with all staffing requirements as stated in 42 C.F.R. Section 405 .2100."*

In Section VII.10, pages 35-36, the applicant provides the following table that illustrates the current and projected number of direct care staff per shift offered:

	Shift Times	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Morning	6am to 10:30am	8	8	8	8	8	8
Afternoon	11am to 4pm	8	8	8	8	8	8

In Section V.4, page 27, the applicant states that Dr. Edward Hoehn-Saric, currently serves as the Medical Director of DC of Richmond County and he has expressed his willingness to continue serving in that role.

The applicant documents the availability of adequate health manpower and management personnel, including the medical director, for the provision of dialysis services. Therefore, the application is conforming to this criterion.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

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In Section V.1, page 25, the applicant provides a list of providers of the necessary ancillary and support services. Acute dialysis in an acute care setting, emergency care, diagnostic evaluation services, X-ray services, blood bank and vascular surgery will be provided by Sandhills Regional Medical Center. See Exhibit 9 for a copy of the hospital transfer agreement with Sandhills Regional Medical Center and Exhibit 10 for a copy of the Transplant Agreement with UNC Hospital. The applicant adequately demonstrates the necessary ancillary and support services are 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

NA

- (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
  - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;

- (iii) would cost no more than if the services were provided by the HMO; and
- (iv) would be available in a manner which is administratively feasible to the HMO.

NA

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

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;

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In Section VI.1(a), page 29, the applicant states DC of Richmond County, by policy, will make dialysis services available to all residents in its service area without qualifications.

In Section VI.1(b), page 29, the applicant reports that 92.0% of the patients who received treatments at DC of Richmond County 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 the existing facility:

<b>DC of Richmond County Payor Mix</b>	
<b>Source of Payment</b>	<b>Percentage</b>
Medicare	25.7%
Medicaid	3.0%
Medicare/Medicaid	32.6%
Commercial Insurance	5.0%
VA	3.0%
Medicare/Commercial	30.7%
<b>Total</b>	<b>100.0%</b>

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

<b>County</b>	<b>2010 Total # of Medicaid Eligibles as % of Total Population *</b>	<b>2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *</b>	<b>2008-2009 % Uninsured CY (Estimate by Cecil G. Sheps Center) *</b>
Richmond	28.0%	12.4%	21.4%
Scotland	30.0%	12.9%	21.5%
Anson	23.0%	10.9%	22.3%
Statewide	17%	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 2011 only 5.8% of all newly-diagnosed ESRD patients (incident ESRD patients) in North Carolina's Network 6 were under the age of 35.<sup>1</sup>

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data are available by age, race or gender. However, a direct comparison to the applicant's current payor mix would be of little value. The population data by age, race or gender do not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

According to the CMS website, in 2008, about 95% of dialysis patients were covered by Medicare. About 25% of the Medicare-covered patients

<sup>1</sup> Southeastern Kidney Council ESRD Network 6 2011 Annual Report; Table 3, page 16.

had employer group health plans as primary insurance, with Medicare as the secondary payer. Also, the CMS website states:

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

*Almost half (46.6%) of the incident patients in 2004 were between the ages of 60 and 79. These distributions have remained constant over the past five years. While the majority of dialysis patients are White, ESRD rates among Blacks and Native Americans are disproportionately high. While Blacks comprise over 12% of the national population, they make up 36.4% of the total dialysis prevalent population. In 2004 males represented over half of the ESRD incident (52.6%) and prevalent (51.9%) populations.”<sup>2</sup>*

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

*“Nine of ten prevalent hemodialysis patients had some type of Medicare coverage in 2010, with 39 percent covered solely by Medicare, and 32 percent covered by Medicare/Medicaid. ... Coverage by non-Medicare insurers continues to increase in the dialysis population, in 2010 reaching 10.7 and 10.0 percent for hemodialysis and peritoneal dialysis patients, respectively.”<sup>3</sup>*

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

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<sup>2</sup> <http://www.cms.gov/Medicare/end-stage-renal-disease/esrdnetworkorganizations/downloads/esrdnetworkprogrambackgroundpublic.pdf>

<sup>3</sup> United States Renal Data System 2012 USRDS Report, Chapter 1, page 225:  
[http://www.usrds.org/2012/pdf/v2\\_ch1\\_12.pdf](http://www.usrds.org/2012/pdf/v2_ch1_12.pdf).

<b>ESRD Spending by Payor<sup>4</sup></b>		
Payor	Spending in Billions	% of Total Spending
Medicare Paid	\$29.6	62.32%
Medicare Patient Obligation	\$4.7	9.89%
Medicare HMO	\$3.4	7.16%
Non-Medicare	\$9.8	20.63%

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

<b>Number and Percent of Dialysis Patients by Age, Race, and Gender</b>		
	# of ESRD Patients	% of Dialysis Population
<b>Age</b>		
0-19	89	1.0%
20-34	451	4.8%
35-44	773	8.3%
45-54	1529	16.4%
55-64	2370	25.4%
65-74	2258	24.2%
75+	1872	20.0%
<b>Gender</b>		
Female	4,237	45.35%
Male	5,105	54.65%
<b>Race</b>		
African-American	5,096	54.55%
White	4,027	43.11%
Other	219	2.3%
<b>Total</b>	<b>9,342</b>	<b>100.0%</b>

Source: SKC Network 6, which includes North Carolina, South Carolina and Georgia.<sup>5</sup>

DC of Richmond County 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

<sup>4</sup> United States Renal Data System 2012 USRDS Report, Chapter 11, page 340:  
[http://www.usrds.org/2012/pdf/v2\\_ch11\\_12.pdf](http://www.usrds.org/2012/pdf/v2_ch11_12.pdf)

<sup>5</sup> Southeastern Kidney Council ESRD Network 6 2011 Annual Report; Table 3, page 16.



programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

In Section VI.1(f), page 30, the applicant states,

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

In Section VI.6 (a), page 32, the applicant states, *“There have been no civil rights access complaints filed within the last five years.”*

The application is conforming to this criterion.

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

C

In Section VI.1(c), page 30, the applicant provides the projected payor mix for the proposed services at the existing facility, as follows:

DC OF RICHMOND COUNTY PAYOR MIX	
SOURCE OF PAYMENT	PERCENTAGE
Medicare	25.7%
Medicaid	3.0%
Medicare/Medicaid	32.6%
Commercial Insurance	5.0%
VA	3.0%
Medicare/Commercial	30.7%
<b>Total</b>	<b>100.0%</b>

As illustrated in the table above as compared to the table on page 29 of the application, the applicant does not project a change in its payor mix.

In Section VI.1(a), page 29, the applicant states,

*“DC Richmond County 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. DC Richmond County works with patients who need transportation, when necessary.”*

The applicant demonstrates that medically underserved populations will continue to 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(a), page 31, the applicant states that:

*“Patients with End Stage Renal Disease have access to dialysis services upon referral to a Nephrologist with privileges at DC Richmond County. These referrals most commonly come from primary care physicians or specialty physicians in Richmond, Moore and Scotland Counties. Patients, families and friends can obtain access by contacting a Nephrologist with privileges at the facility. Should a patient contact the DC Richmond County directly or indirectly, the patient is referred to a qualified Nephrologist for evaluation and subsequent admission if medically necessary. Patients from outside the DC Richmond County catchment area requesting transfer to this facility are processed in accordance with the DC Richmond County transfer and transient policies which comprise **Exhibit 13**. The patient, again, is referred to a qualified Nephrologist for evaluation and subsequent admission, if medically necessary.”*  
[Emphasis in original]

The applicant adequately demonstrates that it provides a range of means by which a person can access services at DC Richmond County. 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(a), page 27, the applicant states,

*“DC of Richmond County has offered the facility as a clinical learning site for nursing students from Richmond County Community College.”*

Exhibit 11 contains a copy of a letter dated March 10, 2010 from DC of Richmond County to the President of Richmond Community College offering DC of Richmond County as a clinical training site for nursing students from Richmond Community College. The information provided in Section V.3 is reasonable and credible and supports a finding of conformity with this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to add three dialysis stations to its existing facility for a total of 30 certified dialysis stations upon completion of this project.

According to the January 2014 SDR, DC of Richmond County is one of 2 existing dialysis facilities in Richmond County. Both facilities are owned by the same parent. See the following table.

Facility	Number of Dialysis Stations as of December 16, 2013				
	Certified	CON Issued/Not Certified	Decision Rendered (Conditional Approvals)	Decision Pending	Total
DC of Richmond County	27	0	0	0	27
Sandhills Dialysis	12	0	0	0	12

Source: January 2014 SDR

As of June 30, 2013, the utilization rate of DC of Richmond County was 3.4074 patients per station or 85.19% of capacity. This utilization rate was calculated

based on 92 in-center dialysis patients and 27 certified dialysis stations (92 patients / 27 stations = 3.4074 patients per station;  $3.4074/4 = 0.8519$ ). The other facility in Richmond County is certified for 12 stations and is currently serving 30 in-center patients, which is a utilization rate of 62.5% ( $30/12 = 2.5$ ;  $2.5/4 = 0.625$ ). This facility has only been in existence since September 2012.

In Section V.7, page 28, the applicant discusses how any enhanced competition in the service area will have a positive impact on the cost-effectiveness, quality and access to the proposed services. 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. DC of Richmond County is one of two dialysis facilities in Richmond County. The other facility, located in Rockingham in Richmond County, is owned and operated by Total Renal Care of North Carolina.*

...

*The bottom line is that patient selection is the determining factor, as the patient will select the provider that gives them the highest quality service and best meets their needs. DC of Richmond County provides access to all qualified Nephrologists to admit his or her patients. None of the Nephrologists associated with Fresenius Medical Care have sought admitting privileges at DC of Richmond County.”*

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

The applicant adequately demonstrates that any enhanced competition will have a positive impact on the cost-effectiveness, quality and access to the proposed services based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need to add three additional stations to the existing facility based on the facility need methodology. The applicant also demonstrates that the proposed project is a cost-effective alternative to meet the need to provide additional access to DC of Richmond County patients;
- The applicant adequately demonstrates it will continue to provide quality services.
- The applicant adequately demonstrates it will continue to provide adequate access to medically underserved populations.

Therefore, the application is conforming to this criterion.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

The applicant currently provides dialysis services at DC of Richmond County. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, DC of Richmond County has operated in compliance with all Medicare Conditions of Participation within the eighteen months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

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

C

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

**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 II.1, page 10, the applicant states the utilization rate is reported in the January 2014 SDR provided in Exhibit 7. As of June 30, 2013, the

utilization rate of DC of Richmond County was 3.4074 patients per station. This utilization rate was calculated based on 92 in-center dialysis patients and 27 certified dialysis stations (92 patients / 27 stations = 3.4074 patients per station).

(2) *Mortality rates;*

-C- In Section IV.2, page 23, the applicant reports the 2011, 2012 and 2013 facility mortality rates as 13.0%, 23.2% and 15.3%, respectively.

(3) *The number of patients that are home trained and the number of patients on home dialysis;*

-C- In Section IV.3, page 23, the applicant states that as of December 21, 2013, DC of Richmond County had 9 home-trained patients.

(4) *The number of transplants performed or referred;*

-C- In Section IV.4, page 24, the applicant states, "DC of Richmond County had twenty-one patients for transplant evaluation in 2013 and ... no patients who received transplants in 2013."

(5) *The number of patients currently on the transplant waiting list;*

-C- In Section IV.5, page 24, the applicant states, "DC of Richmond County has two 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 24, the applicant states that DC of Richmond County had 193 hospital admissions in 2013, 44 (22.8%) of which were dialysis related and 149 (77.2%) of which 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 24, the applicant states that there were no patients dialyzing with infectious diseases as of December 31, 2013. The applicant also states that the number of patients treated with infectious disease who have converted to infectious status within the last year is zero.

(b) *An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following*

*information requested on the End Stage Renal Disease (ESRD) Treatment application form:*

(1) *For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100.*

-NA- DC of Richmond County is an existing 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- DC of Richmond County is an existing facility.

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

-NA- DC of Richmond County is an existing facility.

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

-C- See Exhibit 8, in which the applicant provides copies of written policies and procedures for back up electrical service in the event of a power outage.

(5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated*

*should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*

-NA- DC of Richmond County is an existing facility.

(6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*

-C- In Section XI.6(g), page 52, the applicant states, “*DC of Richmond County has and will continue to operate within the applicable laws and regulations pertaining to staffing and fire safety equipment, physical environment, and other relevant health safety requirements.*”

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

-C- In Section III.7, pages 20-21 the applicant provides the projected patient origin, including all assumptions, the methodology by which the patient origin is projected, as illustrated in the table below.

**Projected Dialysis Patient Origin**

COUNTY	Operating Year 1 2015		Operating Year 2 2016		County Patients as a Percent of Total	
	In-Center Patients	Home Dialysis Patients	In Center Patients	Home Dialysis Patients	Year 1	Year 2
Richmond	83	5	86	5	83.1%	83.6%
Anson	1	0	1	0	0.9%	0.9%
Scotland	6	2	6	2	7.5%	7.3%
Robeson	0	2	0	2	1.9%	1.8%
South Carolina	6	1	6	1	6.6%	6.4%
TOTAL	96	10	99	10	100%	100%

See Section III.7, pages 20-21 of the application and the discussion in Criterion (3) with regard to the methodology and assumptions the applicant uses to project patient origin which is incorporated hereby as if set forth fully herein.



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

-NA- DC of Richmond County is an existing facility.

(9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.*

-C- In Section II. 1, page 12, the applicant states, “*Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Richmond County will admit and provide dialysis services to patients who have no insurance or other source of payment, if payment for dialysis services is made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.*”

**.2203 PERFORMANCE STANDARDS**

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

-NA- DC of Richmond County is an existing 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- The applicant projects to have 96 in-center patients by the end of year one for a utilization rate of 80.0% or 3.2 patients per station per week [  $96 / 30 = 3.2 / 4.0 = 0.8$  or 80.0%]. As of June 30, 2013, the utilization rate of DC of Richmond County was 3.4074 patients per station. This utilization rate was calculated based on 92 in-center dialysis patients and 27 certified dialysis stations (  $92 \text{ patients} / 27 \text{ stations} = 3.4074$  patients per station). See Criterion (3) for additional discussion regarding projected utilization which is incorporated hereby as if set forth fully herein.

**.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 25, states patients will be referred to Sandhills Regional Medical Center for diagnostic and evaluation services.

(2) *maintenance dialysis;*

-C- The table in Section V.1, page 25, states the applicant will provide in-center maintenance dialysis at DC of Richmond.

(3) *accessible self-care training;*

-C- The table in Section V.1(d), page 25, states that in-center hemodialysis, CAPD and CCPD will be provided by DC of Richmond.

(4) *accessible follow-up program for support of patients dialyzing at home;*

-C- The applicant addresses accessible follow-up program for support of patients dialyzing at home in Section V.2(d), page 26. The applicant states:

*“DC of Richmond County provides protocols and routines for patient follow-up. The social workers and dieticians contact the home-trained patients monthly. The patients are supported by monthly visits to their Board Certified Nephrologist for examination. The Home Training Nursing teammates perform monthly medication reviews, nursing assessments and laboratory review of blood work in order to continuously monitor the well being of home patients. Patient’s blood chemistries are sent to a Medicare certified laboratory where they are analyzed. The results are reviewed by the teammates for adequacy and then reviewed by the dietitian and Nephrologist. Home trained patients are monitored by our Quality Management team.”*

(5) *x-ray services;*

- C- The table in Section V.1, page 25, states patients will be referred to Sandhills Regional Medical Center for x-ray services.
- (6) *laboratory services;*
- C- The table in Section V.1, page 25, states patients will be referred to Dialysis Laboratories for routine and special laboratory services.
- (7) *blood bank services;*
- C- The table in Section V.1, page 25, states patients will be referred to Sandhills Regional Medical Center for blood bank services.
- (8) *emergency care;*
- C- The table in Section V.1, page 25, states patients will be referred to Sandhills Regional Medical Center for emergency care.
- (9) *acute dialysis in an acute care setting;*
- C- The table in Section V.1, page 25, states patients will be referred to Sandhills Regional Medical Center for acute dialysis in an acute care setting.
- (10) *vascular surgery for dialysis treatment patients;*
- C- The table in Section V.1, page 25, states dialysis patients will be referred to Sandhills Regional Medical Center for vascular surgery.
- (11) *transplantation services;*
- C- The table in Section V.1, page 25, and Exhibit 10 states patients will be referred to UNC Hospital for transplantation services. See Exhibit 10 for documentation of transplantation agreement.
- (12) *vocational rehabilitation counseling and services; and*
- C- The table in Section V.1, page 25, states patients will be referred to Vocational Rehabilitation for vocational rehabilitation counseling and services.
- (13) *transportation.*

- C- The table in Section V.1, page 25, states patients will be 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.*
  - C- In Section VII.1, page 33, the applicant provides the current staffing for DC of Richmond County. The applicant states, “*The facility complies with all staffing requirements as stated in 42 C.F.R. Section 405.2100 as evidenced below.*” DC of Richmond County plans for two dialysis shifts including direct care staffing of eight direct care personnel per shift on Monday through Saturday for both shifts. (See application page 36.)
- (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 34, the applicant refers to Exhibit 16 for a copy of the training program description/outline. Exhibit 16 contains a copy of DaVita’s Training Programs for New Patient Care Provider Teammates. Exhibit 23 contains the DC of Richmond County Annual In-Service Calendar.