

## ATTACHMENT – REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA – Conditional

NC – Nonconforming

NA = Not Applicable

Decision Date: June 16, 2015

Findings Date: June 16, 2015

Project Analyst: Tanya S. Rupp

Team Leader: Lisa Pittman

Project ID #: H-11017-15

Facility: Dialysis Care of Richmond County

FID #: 955843

County: Richmond

Applicant: Total Renal Care of North Carolina, LLC

Project: Add two stations to the existing facility for a total of 27 in-center dialysis stations upon completion of this project, Project ID #H-10271-14 (add three stations to existing facility), N-10345-14 (relocate one station to Dialysis Care of Hoke County), and H-11001-15 (relocate four stations to Sandhills Dialysis Center).

### 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 d/b/a Dialysis Care of Richmond County (DC Richmond) is currently certified for 27 in-center dialysis stations, according to Table A in in the January 2015 Semi-Annual Dialysis Report (SDR). There are a total of four projects that impact this facility, including the current proposal. The table below illustrates those projects:

PROJECT ID #	DESCRIPTION	# STATIONS ADD (DELETE)	TOTAL
<b># of in-center dialysis stations as of June 30, 2014 (January 2015 SDR)</b>			<b>27</b>
H-10271-14	Add three stations	3	30
N-10345-14	Transfer 1 station to another facility	(1)	29
H-11001-15	Transfer 4 stations to another facility	(4)	25
H-11017-15	Add two stations	2	27

The 2015 State Medical Facilities Plan (2015 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2015 SDR, the county need methodology shows there is no need for an additional dialysis facility or for any additional dialysis stations in Richmond County. However, according to the facility need methodology, an applicant for dialysis stations is eligible to apply for additional dialysis stations if the utilization rate for the dialysis facility, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. In this application, DC Richmond is eligible to apply for additional stations in its existing facility based on the facility need methodology, because the utilization rate is 3.63 patients per station, or 90.7%. This utilization rate was calculated based on 98 in-center dialysis patients and 27 certified dialysis stations as of June 30, 2014 (98 patients / 27 stations = 3.63 patients per station). See the following table, from Section III.1, page 19 of the application, and the June 2014 and January 2015 SDRs:

**APRIL 1 REVIEW-JANUARY SDR**

Required SDR Utilization	80%	
Center Utilization Rate as of 6/30/14	90.74%	
Certified Stations	27	
Pending Stations	3	
<b>Total Existing and Pending Stations</b>	<b>30</b>	
In-Center Patients as of 6/30/14 (SDR2)	98	
In-Center Patients as of 12/31/13 (SDR1)	93	
<b>Step</b>	<b>Description</b>	<b>Result</b>
(i)	Difference (SDR2 - SDR1)	5
	Multiply the difference by 2 for the projected net in-center change	10
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/13	0.1075
(ii)	Divide the result of step (i) by 12	0.0090
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/14 until 12/31/14)	0.0538
(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	103.2688
(v)	Divide the result of step (iv) by 3.2 patients per station	32.2715
	and subtract the number of certified and pending stations as recorded in SDR2 to determine the number of stations needed	<b>2</b>

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.*” As shown in the table above, based on the facility need methodology for dialysis stations, DC Richmond has a need for two additional stations. The applicant proposes to add two new stations and, therefore, the application is consistent with the facility need determination for dialysis stations.

## **Policies**

Policy GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES is not applicable to this review, because the applicant is not proposing a capital expenditure greater than \$2 million. However, Policy GEN-3: BASIC PRINCIPLES, on page 38 of the 2015 SMFP, is applicable to this review. The policy 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 - The applicant describes how it believes the proposed project would promote safety and quality in Section II, pages 17 - 18, Section III, pages 23 - 24, Section V, page 30, Section XI.6(g) pages 58 - 59, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section V, page 30, Section VI, pages 31 - 34, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value – The applicant describes how it believes the proposed project would maximize healthcare value in Section III, page 23 and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the need identified in the 2015 SMFP. Therefore, the application is consistent with Policy GEN-3

## **Conclusion**

In summary, the applicant adequately demonstrates that its proposal to add two dialysis stations to its existing facility is consistent with the facility need determination in the January 2015 SDR and is consistent with Policy GEN-3. 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

DC Richmond County proposes to add two stations to the existing facility, for a facility total of 27 stations upon project completion. The January 2015 SDR reports that, as of June 30, 2014, DC Richmond County had 98 patients dialyzing on 27 stations, which is a utilization rate of 90.7% [ $98 / 27 = 3.63$ ;  $3.63 / 4 = 0.907$ ].

**Population to be Served**

In Section III.7, page 21, the applicant identifies the patient population to be served at DC Richmond County during the first two years of operation following project completion, as illustrated in the following table:

COUNTY	OPERATING YEAR 1 2016		OPERATING YEAR 2 2017		COUNTY PATIENTS AS % OF TOTAL	
	IN-CTR.	HOME	IN-CTR.	HOME	YEAR 1	YEAR 2
Richmond	95	8	99	9	89.6%	90.0%
Scotland	6	1	6	1	6.1%	5.8%
Anson	1	1	1	1	1.7%	1.7%
South Carolina	3	0	3	0	2.6%	2.5%
Total	105	10	109	11	100.0%	100.0%

In Section II, pages 12 - 15, and in Section III.7, pages 21 – 23, the applicant provides the assumptions and methodology it uses to project the proposed in-center and home trained patient utilization of DC Richmond County following the addition of two dialysis stations.

The applicant adequately identifies the population it proposes to serve.

**Demonstration of Need**

**In-Center Patients**

In Section II.1, pages 12 – 13, and Section III.7, pages 21 - 22, the applicant states:

*“Dialysis Care of Richmond County (DC of Richmond County) had 98 in-center patients as of June 30, 2014 based on information included in Table A of the January 2015 Semiannual Dialysis Report (SDR). This is a station utilization rate of 90.74% based on the 27 certified stations. Total Renal Care of North Carolina, LLC submitted a CON application on September 15, 2014 to expand DC of Richmond County by three stations. That CON application was approved, leaving the DC of Richmond County with 30 dialysis stations.*

*Total Renal Care of North Carolina submitted a CON application on February 16, 2015 to transfer four stations from DC of Richmond County to Sandhills Dialysis. Once that CON application is approved and the four stations are transferred to Sandhills Dialysis, there will be 26 stations remaining at DC of Richmond County. The application was for the transfer of four stations, but did not include the transfer of any patients from DC of Richmond County to Sandhills Dialysis.*

*As of June 30, 2014, 88 of the in-center patients lived in Richmond County, 6 of the in-center patients lived in Scotland County, one in-center patient lived in Anson County and three in-center patients lived in South Carolina.”*

In Section III.7, page 22, the applicant projects growth only of the Richmond County patient population, and then adds back the remaining patient population after the growth projections. In its growth projections, the applicant applies the Five Year Average Annual Change Rate found in the January 2015 SDR for Richmond County, which is 3.5%. Therefore, beginning with 88 Richmond County patients reported as of June 30, 2014, the applicant projects a utilization rate of 97% by the end of the first year of operation following the addition of stations, as illustrated below:

- Calculate growth for six months from June 30, 2014 to December 1, 2014:  $88 \times 1.0175 = 89.54$
- $89.54 \times 1.035 = 92.67$  (1/1/15 – 12/31/15)
- $92.67 \times 1.035 = 95.92$  (1/1/16 – 12/31/16; Operating Year One)
- $95.92 \times 1.035 = 99.27$  (1/1/17 – 12/31/17; Operating Year Two)

Thus, in Operating Year One, the applicant projects to serve 105 in-center patients on 27 dialysis stations [95 Richmond County patients, 6 Scotland County patients, 1 Anson County patient, and 3 South Carolina patients). This is a 97% utilization rate, or 3.8 patients per station [ $105 / 27 = 3.89$ ;  $3.89 / 4 = 0.972$ ]. In Operating Year Two, the applicant projects to serve 109 in-center patients on 27 stations, for a utilization rate of 101% [ $109 / 27 = 4.03$ ;  $4.03 / 4 = 1.01$ ]. By the end of the second year of operation, the facility will be overcrowded.

In addition, the January 2015 SDR reports that Sandhills Dialysis Center, the only other dialysis facility in Richmond County and operated by the same parent company as DC Richmond County, was operating at 70.83% utilization, with 34 patients on 12 certified stations. It would appear that Sandhills Dialysis Center is underutilized, while DC Richmond County is projected to be overcrowded. However, facility census data submitted to the North Carolina Medical Facilities Planning Section indicate that Sandhills Dialysis Center reported the following growth in patient census from June 30, 2014 to April 30, 2015:

**Sandhills Dialysis Center Census, June 30, 2014 – April 30, 2015**

DATE	# PATIENTS	# STATIONS	% UTILIZATION
June 30, 2014	34	12	70.83%
December 30, 2014	51	12	106.25%
April 30, 2015	51	12	106.25%

Thus, following completion of Project ID #H-11001-15 and this project, utilization of both Richmond County dialysis facilities will be consistent with the standards promulgated in 10A NCAC 14C .2203(b).

### Home Trained Patients

In Section II.1, page 15, and Section III.7, page 22, the applicant states:

*“It is reasonable to assume that the DC of Richmond County home-training program will grow at a rate of at least one patient during the current operating year and operating years one and two. DC of Richmond County had a total of 8 home-trained patients as of June 30, 2014. It is projected that the census will grow to 9 home-trained patients in 2015, 10 home-trained patients in 2016 and 11 home-trained patients in 2017.”*

### Access to Services

In Section VI, page 31, 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 without regard to race, sex, age, handicap, or ethnic and socioeconomic groups of patients in need of dialysis regardless of their ability to pay.”*  
[sic]

In Section X, page 49, the applicant projects that 88.5% of its payments will be from Medicare or Medicaid; and 3.2% by VA. The applicant adequately demonstrates the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

### Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need that population has for the addition of two dialysis stations at DC Richmond County, and the extent to which all residents of the area, including underserved groups, are likely to have access to the dialysis services proposed. Therefore, the application is conforming to this criterion.

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

- (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, page 23, the applicant states:

*“There were only two alternatives of meeting the needs of the proposed project considered. [sic] The first was to do nothing. This alternative was dismissed since the facility is rapidly growing. The second was to apply for the two-station expansion. We chose the second alternative in order to help meet the growing demand for dialysis services at the DC Richmond County facility.”*

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

The applicant adequately demonstrates that the proposal is its least costly or most effective alternative to meet the need to add two dialysis stations to the existing facility. Consequently, the application is conforming to this criterion and is 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 its certificate of need application.**
- 2. Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Richmond County shall develop and operate no more than two additional dialysis stations for a total of no more than 27 certified stations following completion of this project and Project ID #H-10271-14 (add three stations to existing facility), Project ID #N-10345-14, (transfer one station to Dialysis Care of Hoke County), and Project ID# H-11001-15 (transfer four stations to Sandhills Dialysis), 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 two additional dialysis stations for a total of no more than 27 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 Agency in writing prior to the 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, page 41, the applicant states that project will incur no capital cost for the project, since it does not call for purchase of dialysis chairs, equipment, furniture, or supplies, and there is no facility upfit required to make the additional dialysis stations operational.

In Section IX.3, page 45, the applicant projects no working capital (start-up and initial operating expenses) associated with the proposed project, since the facility is currently operational and the application is for the addition of two stations.

In Section X.1, page 47, the applicant provides the allowable charges per treatment for each payment source for DC Richmond County, as illustrated below in the table.

DC RICHMOND COUNTY	
PAYOR	CHARGE /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 48 and operating expenses in Section X.4, pages 52 - 53 of the application. In Section X.2 - X.4, pages 48 - 52, the applicant reports projected revenues and expenses for DC Richmond County, as illustrated in the following table:

DC RICHMOND COUNTY		
	OPERATING YEAR 1	OPERATING YEAR 2
Total Net Revenue	\$5,096,963	\$5,291,868
Total Operating Costs	\$4,133,937	\$4,280,459
<b>Net Profit</b>	<b>\$ 963,026</b>	<b>\$1,011,409</b>

The applicant projects that revenues will exceed operating expenses in each of the two operating years following project completion. The assumptions used in preparation of the proformas, including the number of projected treatments are reasonable, credible and adequately supported. In Section VII.1, page 36 and Section X.5, page 53, the applicant provides projected staffing and salaries. The applicant provides adequate staffing to provide dialysis treatments for the number of patients projected. See Section X of the application for the applicant's assumptions.



In summary, the applicant projects no capital cost for this project, and adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

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

C

Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Richmond County proposes to add two stations to DC Richmond County, pursuant to the facility need methodology. Total Renal Care of North Carolina, LLC is the only provider of ESRD services in Richmond County, operating DC Richmond County and Sandhills Dialysis, located in Rockingham.

The applicant adequately demonstrates the need to add two stations to DC Richmond County based on the projected number of in-center patients to be served and the projected growth in the dialysis patient population in Richmond County.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved dialysis stations in Richmond County. Consequently, the application is conforming to this criterion.

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

C

In Section VII.1, page 36, the applicant provides projected staffing for DC Richmond County following the addition of two stations, as illustrated in the following table:

<b>DC RICHMOND COUNTY FTE POSITIONS</b>	
RN	5.0
HTRN	1.0
PCT	11.0
Bio-Med Tech	1.0
Admin.	1.0
Dietician	1.0
Social Worker	1.0
Unit Secretary	1.0
Reuse	1.0
<b>Total FTEs</b>	<b>23.0</b>

The applicant states compliance with all staffing requirements in 42 C.F.R. Section 494 (formerly 405.2100). Direct care staffing by shift is provided in Section VII.10 on page 39.

DC Richmond County is an existing facility and is currently fully staffed. The applicant proposes to add two dialysis stations with this application, and proposes one additional patient care technician FTE position. In Section V.4, page 29, the applicant identifies the Medical Director for DC Richmond County as Dr. Edward Hoehn-Saric. In Exhibit 13 the applicant provides a March 13, 2015 letter from Dr. Hoehn-Saric indicating the doctor's support for the project and willingness to continue to serve as Medical Director.

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

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

### C

In Sections V.1 and V.2, pages 27 - 28, the applicant lists the providers of the necessary ancillary and support services that will serve the patients dialyzing at DC Richmond County. Sandhills Regional Medical Center provides emergency services, acute dialysis services, diagnostic and evaluation services, X-ray services, blood bank services, and vascular surgery services. The other services are provided by the individual providers listed in the table provided on page 27. In addition, the applicant provides supporting documentation regarding transplantation and pediatric nephrology services in Exhibit 10. The applicant discusses coordination with the existing health care system in Sections V.2 – V.6, pages 28 - 30. The applicant provides supporting documentation of coordination with the existing health care system in Exhibits 12 and 13. The information provided in those sections and exhibits is reasonable and credible and supports a finding of conformity with this criterion.

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

### NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers: (i) would be available under a contract of at least 5 years duration; (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO; (iii) would cost no more

than if the services were provided by the HMO; and (iv) would be available in a manner which is administratively feasible to the HMO.

NA

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

NA

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

C

In Section VI.1, page 31, 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 without regard to race, sex, age, handicap, or ethnic and socioeconomic groups of patients in need of dialysis regardless of their ability to pay.”* [sic]

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

In Section X, page 49, the applicant reports that 88.5% of the patients who received treatments at DC Richmond County had some or all of the services paid for by Medicare or Medicaid in the past year, as shown in the table below:

<b>DC RICHMOND COUNTY HISTORICAL PAYOR MIX</b>	
<b>PAYOR SOURCE</b>	<b>PERCENTAGE</b>
Medicare	23.2%
Medicaid	3.2%
Medicare/Medicaid	28.4%
Commercial Insurance	8.4%
VA	3.2%
Medicare/Commercial	33.7%
<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 County and statewide.

	<b>2010 Total # of Medicaid Eligibles as % of Total Population *</b>	<b>2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *</b>	<b>2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *</b>
Richmond County	28%	12%	21%
Statewide	17%	7%	20%

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

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the dialysis services offered by DC Richmond County. In fact, in 2011 only 5.8% of all newly-diagnosed ESRD patients (incident ESRD patients) in North Carolina's Network 6 were under the age of 35.

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

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

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

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

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

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

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

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

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

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

<b>NUMBER AND PERCENT OF DIALYSIS PATIENTS BY AGE, RACE, AND GENDER*</b>		
	<b># OF ESRD PATIENTS</b>	<b>% OF DIALYSIS POPULATION</b>
<b>Age</b>		
0-19	89	1.0%
20-34	451	4.8%
35-44	773	8.3%
45-54	1529	16.4%
55-64	2370	25.4%
65-74	2258	24.2%
75+	1872	20.0%
<b>Gender</b>		
Female	4,237	45.35%
Male	5,105	54.65%
<b>Race</b>		
African-American	5,096	54.55%
White	4,027	43.11%
Other	219	2.3%
Total	9,342	100.0%

\*Source: SKC Network 6, which includes North Carolina, South Carolina and Georgia.

The applicant demonstrates that medically underserved populations currently have adequate access to services available at DC Richmond County. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

**C**

In Section VI.1(f), page 33, the applicant states, *“DC of Richmond County has no obligation under any applicable federal regulation to provide uncompensated care, community service or access by minorities and handicapped persons...”* In Section VI.6(a), page 35, the applicant states *“There have been no civil rights equal access complaints filed within the last five years.”* The application is conforming to this criterion.

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

C

In Section X, page 49, the applicant provides the projected payor mix for the proposed dialysis services at the facility. The applicant projects no change from the current payor mix. The applicant projects 88.5% of all in-center patients will have some or all of the services paid for by Medicare and Medicaid; and 2.8% of all in-center patients will have services paid for by the VA.

<b>DC RICHMOND COUNTY PROJECTED PAYOR MIX</b>	
<b>PAYOR SOURCE</b>	<b>PERCENTAGE</b>
Medicare	23.2%
Medicaid	3.2%
Medicare/Medicaid	28.4%
Commercial Insurance	8.4%
VA	3.2%
Medicare Commercial	33.7%
Total	100.0%

In Section VI.2, pages 33 - 34, the applicant states the facility currently serves patients who are handicapped, and thus is currently designed and constructed to accommodate handicapped persons. The applicant states the design will not change as a result of this two-station addition.

The applicant demonstrates that the elderly and medically underserved populations will continue to have adequate access to the proposed dialysis services provided by DC Richmond County. Therefore, the application is conforming to this criterion.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section VI.5, pages 34, the applicant describes the range of means by which patients will have access to the proposed dialysis services. The information provided in Section VI.5 is reasonable and credible and supports a finding of conformity with this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Section V.3, page 29, the applicant states DC Richmond County has an existing clinical training agreement with Richmond Community College. Exhibit 12 contains a copy of the existing agreement. The applicant adequately demonstrates that the facility will accommodate the clinical needs of health professional training programs in the proposed service area. Therefore, the application is conforming to this criterion.

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

### C

Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Richmond County proposes to add two dialysis stations to its existing facility, for a total of 27 in-center dialysis stations at DC Richmond County upon completion of this project, Project ID# H-10271-14 (add three stations to existing facility), Project ID# N-10345-14 (relocate one station to Dialysis Care of Hoke County), and Project ID# H-11001-15 (relocate four stations to Sandhills Dialysis Center).

The January 2015 SDR shows that, as of June 30, 2014, there were two operational dialysis facilities located in Richmond County: DC Richmond County and Sandhills Dialysis. Both facilities are operated by Total Renal Care of North Carolina, LLC. In this application, the applicant proposes to add two stations to DC Richmond County pursuant to the facility need methodology.

The applicant adequately demonstrates the need for two additional station at DC Richmond County based on the number of in-center patients it proposes to serve. The January 2015 SDR reports that as of June 30, 2014, DC Richmond was operating at 90% capacity, with 98 patients dialyzing on 27 stations [ $98 / 27 = 3.63$ ;  $3.63 / 4 = 0.9074$ ]. The target utilization is 80% or 3.2 patients per station per week as of the end of the first operating year of the facility, pursuant to 10A NCAC 14C .2203(b).

In Section V.7, page 30, the applicant states that the proposed facility expansion is not intended to be a competitive venture; rather, a response to the needs of the facility and patients. Total Renal Care of North Carolina, LLC is the only provider of dialysis services in Richmond County. See also Sections II, III, V, VI and VII, in which the applicant discusses the cost-effectiveness, quality and access to the proposed services.

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



- The applicant adequately demonstrates the need for the proposed project and that it is a cost-effective alternative. The discussion regarding analysis of need and alternatives found in Criteria (3) and (4) respectively is incorporated herein by reference.
- The applicant adequately demonstrates it will continue to provide quality services. The discussion regarding quality found in Criteria (1) and (20) is incorporated herein by reference.
- The applicant adequately demonstrates it will continue to provide adequate access to medically underserved populations. The discussion regarding access found in Criteria (1) and (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.

### C

In Section I.13 and referenced Exhibits, the applicant identifies the kidney disease treatment centers located in North Carolina owned and operated by the applicant or an affiliated company. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. The application is conforming to this criterion.

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

### C

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

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

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

- (1) Utilization rates;*  
-C- In Sections II and III, pages 12 and 21, the applicant provides the utilization rates for DC Richmond County. As of June 30, 2014, the utilization rate was 90.74% [ $98 / 27 = 3.63$ ;  $36.6 / 4 = 0.9075$ ].
- (2) Mortality rates;*  
-C- In Section IV.2, page 25, the applicant states the mortality rates were 23.2%, 15.3% and 5.0% in 2012, 2013 and 2014, respectively.
- (3) The number of patients that are home trained and the number of patients on home dialysis;*  
-C- In Section IV.3, page 25, the applicant states the facility had six patients who were home trained as of December 31, 2014.
- (4) The number of transplants performed or referred;*  
-C- In Section IV.4, page 26, the applicant states DC Richmond County referred 16 patients for transplant evaluation in 2014. The applicant states no transplants were performed in 2014.
- (5) The number of patients currently on the transplant waiting list;*  
-C- In Section IV.5, page 26, the applicant states DC Richmond County has three patients currently on the transplant waiting list.
- (6) Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*  
-C- In Section IV.6, page 26, the applicant states that there were 137 total hospital admissions in 2014, 6 of which were dialysis related and 131 that were non-dialysis related.
- (7) The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during last calendar year.*  
-C- In Section IV.7, page 26, the applicant states that there were no patients with infectious disease or who were converted to infectious status at DC Richmond County during 2014.

*(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 Richmond County is an existing facility.

(2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*

- (A) timeframe for initial assessment and evaluation of patients for transplantation,
- (B) composition of the assessment/evaluation team at the transplant center,
- (C) method for periodic re-evaluation,
- (D) criteria by which a patient will be evaluated and periodically re- evaluated for transplantation, and
- (E) signatures of the duly authorized persons representing the facilities and the agency providing the services.

-NA- DC 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 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 for a copy of the policies and procedures for back-up electrical service in the event of a power outage for DC Richmond County.

(5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*

-NA- DC 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 58, the applicant states, “Dialysis Care 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 II.1, pages 12 – 14, and Section III.7, pages 21 - 22, the applicant provides the methodology and assumptions to project patient origin as presented in the following table:

COUNTY	OPERATING YEAR 1		OPERATING YEAR 2		COUNTY PATIENTS AS PERCENT OF TOTAL	
	IN-CTR.	HOME PTS.	IN-CTR.	HOME PTS.	YEAR 1	YEAR 2
Richmond	95	8	99	9	89.6%	90.0%
Scotland	6	1	6	1	6.1%	5.8%
Anson	1	1	1	1	1.7%	1.7%
South Carolina	3	0	3	0	2.6%	2.5%
Total	105	10	109	11	100.0%	100.0%

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

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

-NA- DC 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.”*

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

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

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

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

-C- DC Richmond County projects 3.9 patients per station per week as of the end of the first operating year. Assumptions are provided in Section II.1, pages 12 - 13, and

Section III.7, pages 21 - 22. The discussion regarding need found in Criterion (3) is incorporated herein by reference.

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

- C- The applicant provides all assumptions, including the methodology by which patient utilization is projected in Section II.1, pages 12 - 13, and Section III.7, pages 21 - 22. The discussion regarding patient utilization found in Criterion (3) is incorporated herein by reference.

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

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

*(1) diagnostic and evaluation services;*

- C- In Section V.1, page 27, the applicant states patients will receive diagnostic and evaluation services from Sandhills Regional Medical Center.

*(2) maintenance dialysis;*

- C- In Section V.1, page 27, the applicant states patients will receive maintenance dialysis services at the facility.

*(3) accessible self-care training;*

- C- On page 28 the applicant states DC Richmond County provides self-care training for dialysis for its patients.

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

- C- In Section V.2, page 28 the applicant states DC Richmond County provides an accessible follow-up program for support of those patients desiring home dialysis.

*(5) x-ray services;*

- C- In Section V.1, page 27, the applicant states x-ray services will be provided by Sandhills Regional Medical Center.

*(6) laboratory services;*

- C- In Section V.2, page 28, the applicant states laboratory services will be provided by Sandhills Regional Medical Center. On page 27, the applicant also indicates that Dialysis Laboratories will provide laboratory services.

*(7) blood bank services;*

- C- In Section V.1, page 27, the applicant states blood bank services will be provided by Sandhills Regional Medical Center.

*(8) emergency care;*

- C- In Section V.1, page 27, the applicant states emergency care services will be provided by Sandhills Regional Medical Center.

- (9) *acute dialysis in an acute care setting;*  
-C- In Section V.1, page 27, the applicant states acute dialysis services will be provided by Sandhills Regional Medical Center.
- (10) *vascular surgery for dialysis treatment patients;*  
-C- In Section V.1, page 27, the applicant states vascular surgery services will be provided by Sandhills Regional Medical Center.
- (11) *transplantation services;*  
-C- In Section V.1, page 27, the applicant states transplantation services will be provided by UNC. However, Exhibit 10 contains a copy of a transplant agreement with Duke University Health Systems and The Mayo Clinic.
- (12) *vocational rehabilitation counseling and services; and*  
-C- In Section V.1, page 27, the applicant states vocational rehabilitation counseling and services will be provided by “*Vocational Rehabilitation.*” However, the analyst concludes the applicant is referring to the North Carolina Division of Vocational Rehabilitation Services.
- (13) *transportation.*  
-C- In Section V.1, page 27, the applicant states transportation services will be provided by ART Transit.

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

- (a) *To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R., Section 405.2100.*  
-C- In Section VII.1, on page 36, the applicant states that all staffing requirements will be met as stated in 42 C.F.R. Section 494 (formerly 405.2100). The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.
- (b) *To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.*  
-C- In Exhibit 17 the applicant provides a copy of the applicant’s training program outline for new nurses and technicians in dialysis techniques at the facility. Within that policy are guidelines for continuing education and training of DaVita clinical employees.