

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: September 27, 2012

FINDINGS DATE: September 28, 2012

PROJECT ANALYST: Gene DePorter

CON CHIEF: Craig Smith

PROJECT I.D. NUMBER: K-8818-12/ DaVita Healthcare Renal Care, Inc. d/b/a Roxboro Dialysis Center / Relocate and replace the existing 24 dialysis station facility within the same community of Roxboro, NC and add 6 previously approved dialysis stations (Project # K-8573-10) for a total of 30 dialysis stations upon project completion / Person FID # 120225

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

The applicant, DaVita Healthcare Renal Care, Inc. d/b/a Roxboro Dialysis Center [**DVA-RDC**] proposes to relocate its current 24 dialysis station facility [K-8818-12] at Main Street and Madison Blvd. in Roxboro, Person County to a different portion of the existing site. DVA-RDC will add 6 previously approved dialysis stations [Project # K-8573-10] for a total of 30 dialysis stations upon project completion. The applicant does not propose to establish new dialysis stations nor move stations to contiguous counties. Therefore, neither of the need methodologies in the *2012 State Medical Facilities Plan [2012 SMFP]* is applicable to the review.

The North Carolina Semiannual Dialysis Report January 2012, Table A, indicates that Roxboro Dialysis Center is operating at 3.71 patients per station with a utilization rate of 92.71% which exceeds the minimum operating standard. This application is for the relocation of the facility on the same site, which will house 30 dialysis stations upon completion.

POLICY ESRD 2: RELOCATION OF DIALYSIS STATIONS applies and states the following:

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

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

Consequently, there is no change in the inventory in the host county.

In summary, the applicant proposes to relocate on site and make space adjustments within the same square footage to accommodate 24 existing stations and incorporate the 6 approved but not yet developed stations in the town of Roxboro in Person County. Consequently, there is no change in the dialysis station inventory in Person County. POLICY GEN-4: Energy Efficiency and Sustainability for Health Service Facilities does not apply because the capital expenditure for this project does not trigger the > \$2 million capital cost threshold pursuant to G.S. 131E-178. 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

The January 2012 SDR indicates a total of 24 certified dialysis stations and 6 CON approved but not yet certified dialysis stations at DVA-Roxboro Dialysis Center [DVA-RDC]. In this application, DVA-RDC will add the 6 stations previously approved through CON application K-8573-10 for a total of 30 stations upon completion, scheduled to be operational by January 1, 2014.

In application Section III. 7, pages 19-20 the applicant identifies the population it has served since 2010 and the population it proposes to serve during the first two operating years following project completion, as illustrated in the following tables:

Table 1
DVA-RDC Historic and Projected Patient Origin for Operating

Years 2010 through 2012

County	Patient Origin CY 2010		Patient Origin CY 2011		Patient Origin CY 2012*	
	In Center	Home Dialysis	In Center	Home Dialysis	In Center	Home Dialysis
Person	80	6	85	6	86	6
Caswell	7	0	7	0	7	0
Durham	3	0	3	0	3	0
Orange	1	0	1	0	1	0
Alamance	1	0	1	0	1	0
South Boston	1	0	1	0	1	0
Total	93	6	98	6	100	6

Source: Application K-8818-12, Section III, page 19.

* Estimated

Table 2
DVA-RDC Projected Patient Origin for Operating
Years 2013 Through 2015

County	Interim Patient Origin CY 2013		Operating YR 1 CY 2014		Operating YR 2 CY 2015	
Person	88	6	90	6	92	6
Caswell	7	0	7	0	7	0
Durham	3	0	3	0	3	0
Orange	1	0	1	0	1	0
Alamance	1	0	1	0	1	0
South Boston	1	0	1	0	1	0
Total	101	6	103	6	105	6

Source: Application K-8818-12, Section III, 7, page 19.

The applicant projected patient origin for FY 2014 and FY 2015 to be approximately the same. In Operating Year One [2014] the applicant projects that the patients per station ratio will be 3.43. In Operating Year Two [2015] the ratio will be 3.50 patients per station.

Therefore, the applicant has adequately identified the population it will serve.

As noted earlier, in Section III.4, page 18; the need for a replacement facility is based upon the following considerations:

- The current lease will expire in two years,
- One option is to extend the lease and build an extension to the existing building,
- The cost of the building expansion was deemed to be prohibitive,
- The most cost effective alternative is to build a new facility on the existing site.

In Section III.7, pages 19-20, the applicant states the following:

“The Roxboro Dialysis Center had 98 in-center patients as of December 31, 2011 based upon the facility census on that date. This is a stations utilization rate of 102% based on the 24 certified stations and six approved stations. We are applying to relocate the facility. Of the 98 in-center patients, 85 of them live in Person County. Based on the patients and stations above, Roxboro Dialysis Center is projected to have at least 103 in-center patients by the end of operating year one for a utilization rate of 86% or 3.4 patients per station and at least 105 in-center patients by the end of operating year 2 for a utilization of 88% and 3.5 patients per station. We have used the Average Annual Change Rate of 2.0% for the 85 in-center patients who live in Person County for the time period of January 1, 2012 forward to December 31, 2015.”

In addition, DVA-RDC’s projected utilization calculation in project years one and two ending census; is rounded down to the whole number. Utilization at DVA-RDC is expected to be the following:

Operating Year One

103 patients dialyzing on 30 stations = 3.43 patients per station
 $103 / (4 \times 30) = 0.8583$ or 85.00% by 12/31/2014.

Operating Year Two

105 patients dialyzing on 30 stations = 3.50 patients per station
 $105 / (4 \times 30) = 0.8750$ or 87.00% by 12/31/2015.

DVA-RDC currently has 24 certified stations and 6 approved which will be operational upon completion of this project for a total of 30 operational stations by December 31, 2014. The applicant shows in Exhibit 18, a floor plan with a total of 32 stations based upon inclusion of 2 combined Peritoneal/Home Hemodialysis training rooms [PD/HHD]. The applicant indicates that Home Dialysis training will be provided at RDC.

In summary, the application adequately identified the population to be served and demonstrated need for facility relocation. The applicant also indicates that the facility relocation will continue to keep services within 30 miles or less for 100% of the facility’s in-center patients. Therefore, the application is conforming to this criterion for a total of 30 ESRD stations inclusive of one isolation station.

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

NA

The applicant proposes to construct a replacement facility on the same lot as the current facility. It anticipates no changes in service to the patient population.

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

CA

In Section III.9, page 20-21 of the application, the applicant describes the alternatives it considered to meet the need for the proposed services, stating:

“There were only two alternatives of meeting the needs of the proposed project considered. The first was to extend the lease and build an addition to the existing building. This alternative was dismissed since the cost of constructing the building the building expansion would be cost prohibitive. The second was to apply for relocation of the facility to a new state-of-the-art dialysis center. We chose the second alternative since it will give us a new facility at a much reduced cost.”

In supplemental information requested by the Certificate of Need office, the applicant identified that renovation and expansion of the existing structure would be approximately \$680,000 while the cost of a new state-of-the-art building will be approximately \$1,767,214 [the capital cost identified in Section VIII. 1, page 37]. DVA-RDC is proposing a new facility to rectify parking limitations of the existing structure, reduce limitations on future dialysis station growth and to develop a dialysis center that will meet all the current and near-term care patient care improvements.

In summary, the applicant adequately demonstrated its proposal is the least costly and most effective for the alternative chosen to meet the need. The application is conforming to all other statutory and regulatory review criteria, and thus, is approvable.

Therefore, the application is conforming to the criterion and approved subject to the following conditions:

- 1. DaVita Healthcare Renal Care, Inc d/b/a Roxboro Dialysis Center shall materially comply with all representations made in its certificate of need application.**
- 2. DaVita Healthcare Renal Care, Inc d/b/a Roxboro Dialysis Center shall be certified for no more than 30 dialysis stations, which shall include any home hemodialysis or isolation stations.**
- 3. DaVita Healthcare Renal Care, Inc d/b/a Roxboro Dialysis Center shall provide electrical wiring and plumbing through the walls to accommodate the relocation of 24 existing dialysis stations [K-8818-12] and the addition of 6 stations, approved but not certified [K-8573-10] for**

a total of no more than 30 dialysis stations, which shall include any home hemodialysis or isolation stations.

4. **DVA Healthcare Renal Care, Inc. d/b/a Roxboro Dialysis Center, prior to issuance of the certificate of need, shall acknowledge in writing to the Certificate of Need Section acceptance of and agreement to comply with all conditions stated herein.**

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

C

In Section VIII.1, pages 36-37, the applicant projects that the total capital cost of the project will be \$1,767,214. In addition, the provided supplemental information showing the costs for renovation and expansion costs, as shown in the following table:

**Table 3
 DVA Healthcare Renal Care, Inc. d/b/a Roxboro Dialysis Center
 New Facility/Renovation Expansion
 Capital Costs Comparison**

	New Facility	Renovation & Expansion
Construction Contract	\$ 1,068,000	\$450,000
Dialysis Machines	\$ 92,190	\$82,800
(RO) Water Treatment Equipment	\$ 160,000	\$100,000
Equipment/Furniture	\$ 264,518	\$23,800
Architect/Engineering Fees	\$ 85,000	\$ -0-
Dialysis Chairs	\$ 23,080	\$4,800
Chair side Computer Terminals	\$ 29,426	\$9,000
Televisions	\$ 45,000	\$9,600
Total	\$ 1,767,214	\$680,000

In Sections IX.3, page 41, the applicant indicates that there are no start-up or initial operating expenses. In Section VIII, page 38, the applicant states that DVA, Inc. will fund this project from cash reserves. Exhibit 13 contains a funding letter, dated April 12, 2012, from Mr. James K. Hilger, Vice President of Tax for DaVita, Inc., which states:

“I am the Vice President of Tax for DaVita, Inc., the parent and owner of DVA Healthcare Renal Care, Inc. We are submitting a Certificate of Need application to relocate the Roxboro Dialysis Center.

The project calls for a capital expenditure of \$1,767,214. This letter will confirm that DaVita, Inc has committed cash reserves in the total sum of \$1,767,214 for the project capital expenditure. DaVita, will make these funds, along with any other funds that are necessary for the development of the project, available to DVA Healthcare Renal Care, Inc.”

Exhibit 14 contains the audited financial statements for DaVita, Inc. as of December 31, 2011 DaVita, Inc. had \$393,752,000 in cash and cash equivalents and \$8,892,172,000 in total assets. Therefore, the applicant adequately demonstrated the availability of sufficient funds for the capital and working capital needs of the project.

Based on information provided by the applicant in Section X.1, page 42, the dialysis facility’s projected allowable charges per treatment for each payment source are as follows:

**Table 4
 Applicant Project Allowable Charges**

SOURCE OF PAYMENT	CHARGE PER TREATMENT
Private Pay	0
Medicare	\$240.00
Medicaid	\$240.00
Medicare/Medicaid	\$240.00
Commercial Insurance	\$1,313.00
VA	\$240.00
State Kidney Program	0
Medicare/Commercial	\$240.00

The rates shown above are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services. In Sections X.-2 and X.-4, pages 42-46, the applicant reported projected revenues and expenses as follows:

**Table 5
 Roxboro Dialysis Center
 Projected Net Revenues, Operating Expenses and Net Profit
 6/30/2013 to 6/30/2014**

	OPERATING YEAR 1 (7/1/2013 –6/30/2014)	OPERATING YEAR 2 (7/1/2014 –6/30/2015)
Net Revenue	\$5,530,370	\$5,632,767
Total Operating Expenses	\$4,458,184	\$4,550,382
Net Profit	\$1,072,186	\$1,082,385

DVA-RDC projects that revenue will exceed operating expenses in each of the first two operating years. The assumptions used in preparation of the *pro forma*, including the number of projected treatments, are reasonable [See Section X, pages 42-47 of the application for the applicant’s assumptions]. Nationally, DaVita has approximately 1800 dialysis facilities. The corporation has a centralized purchasing department that negotiates national contracts with numerous vendors in order to secure the best product available at the best price. The applicant will be purchasing the equipment for this project under this procedure.

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

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

C

DVA-RDC is the only dialysis facility in Person County. The facility is located in Roxboro and proposes to construct a replacement dialysis facility on the same site to accommodate 24 certified plus 6 approved dialysis stations. Relocation distance is negligible. Therefore patient access will remain the same. The applicant demonstrated the need to construct the replacement dialysis facility. The applicant considered expansion at the current site using the existing pier construction and determined that expansion would be financially prohibitive. DVA-RDC determined that relocation and construction of a new facility would accommodate current need and future growth. The applicant adequately demonstrated that the relocation of the facility will not result in the unnecessary duplication of existing or approved health service capabilities or facilities.

- (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 32, the applicant provides the current and projected staffing for DVA-RDC as shown in the following table:

Table 6
DaVita-Roxboro Dialysis Center
Current and Projected Staffing

	# of Current (FTE) Positions	# of Projected (FTE) Positions
RN	3.0	4.0
HTRN	0.5	0.5
PCT	11.0	13.0
Bio-Med Tech.	0.5	1.0
MD *	Contract	Contract
Administrator	1.0	1.0
Dietitian	0.7	0.8
Social Worker	0.7	0.8
Clerical	1.0	1.0
Total	18.4	22.1

*Note: the Medical Director is a contract Employee.

The applicant indicates a total of 18.40 current FTE positions and future staffing by the end of the first full year of operation of 22.1 FTE staff. The applicant indicates in Section VII.4, page 33; that it does not expect any difficulty in recruiting staff. The information regarding staffing provided in Section VII and the estimated annual salaries and revenues are reasonable and credible. The Medical Director of the facility is Dr. Eugene Kovalik who is a

Board Certified Nephrologist with several years of experience in the care of ESRD patients. The applicant adequately documents the availability of resources, including health manpower and management personnel, for the provision of the services to be provided. 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 application Section V.1, page 24 DVA-RDC provides a listing of those who provide the necessary ancillary and support services. Exhibit 16 contains a copy of an “*Affiliation Agreement*” with Duke University Medical Center for “*Evaluation Services and Kidney Transplant Agreements*.” Section V.4 (b), page 26 is a listing of physicians who have expressed support for the relocation of Roxboro Dialysis Center and who have expressed a willingness to provide medical coverage for ESRD patients. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health system. Therefore, the application is conforming to this criterion.

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

NA

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

NA

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person

proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C

In application Section XI the applicant proposes to construct a new facility on a 1.5 acre lot [not currently zoned for dialysis facility use-reference Exhibit 16 for conditional use permit] adjacent to the current site. In Section XI, 6 (h), page 54 the applicant provides the current and projected square footage allocation by Ancillary and Treatment Area. The square footage of the current and projected replacement facility are the same. The estimated construction cost is \$1,767,214. The cost per SF is approximately \$185.

Table 7
DVA-RDC Square Footage-Current and Proposed

Ancillary Areas	Current Facility	Proposed Facility
Administration, Reception, Lobby, Elevator	309	309
Public Lobby	479	479
Mechanical Equipment	56	56
Biomedical	130	130
General Storage/Medical Records	386	386
Exam/Treatment/Medical Offices	672	672
Staff Lounge/Lockers	342	342
RO	928	928
Handicap Bathrooms, Dock and Walkways	371	371
Sub-Total	3,673	3,673
Treatment Areas		
Nurses Station/Utility		
Dialysis Stations	4,182	4,182
Patient Home Training	0	0
Isolation Room	116	116
Patient Bath/Corridors	937	937
Sub-Total	5,887	5,887
Total Square Feet	9,560	9,560
Square Feet / Station	139	139

In Section XI, 6 (d), page 52 the applicant states the following in reference to facility energy efficiency;

“The facility is constructed of energy efficient glass, mechanically operated patient access doors and energy efficient cooling and heating.”

In Section XI, 6 (e) and (f), page 52 respectively, the applicant states the following in reference to power service and water supply;

“The facility is located in an area that is supplied by potable city water. The relocation of the facility and dialysis stations will not materially affect quantity of water or sewer used by the facility.

The site is currently served by standing power service.

The applicant adequately addresses energy efficiencies and that costs will not unduly increase the costs and charges of providing the proposed services. See Criterion (5) for discussion of costs and charges.

Therefore, the applicant is conforming with this criterion.

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

C

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 as of CY 2005 and June 2010, respectively. The data in the table were obtained on June 6, 2012. More current data, particularly with regard to the estimated uninsured percentages, was not available.

**Table 9
 Percent of Medicaid Eligible and Percent Uninsured by County**

County	CY 2005 Total # of Medicaid Eligible as % of Total Population	CY 2005 Total # of Medicaid Eligible Age 21 and older as % of Total Population	% Uninsured CY 08-09 (Estimate by Cecil G. Sheps Center)
Person	18.0%	8.3%	18.0%
Caswell	21.0%	11.0%	20.0%
Durham	16.0%	6.0%	20.1%

Statewide	17.0%	6.8%	19.7%
-----------	-------	------	-------

Source: www.ncdhhs.gov/dema-Medicaid-Eligible-Person, Caswell, Durham Counties, June 2010.

The majority of Medicaid eligible is 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 the DVA-RDC.

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 applicants' current payer 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.

In Section VI.1 (a), page 28, the applicant states that Roxboro Dialysis Center provides services to all residents "without qualifications." Furthermore, on page 29, the applicant states:

"Roxboro Dialysis Center makes every reasonable effort to accommodate all of its patients; especially those with special needs such as the handicapped, patients attending school or patients who work. Roxboro Dialysis Center provides dialysis six days per week with two patient shifts per day to accommodate patient need. The facility also operates a third shift Monday, Wednesday and Friday."

"Roxboro Dialysis Center 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."

In Section VI.1 (d), page 29, the applicant states the following:

"The Roxboro Dialysis Center maintains an open-door policy of accepting all patients, regardless of ability to pay, who develop end stage renal disease while residing in the service area of the Roxboro Dialysis Center."

In Section VI.1. (c), page 29 the applicant reports the current and projected payer mix for DVA-RDC, as shown in the following table. The applicant is not projecting any change in reimbursement.

Table 8
DVA-RDC Payer Mix
Historic and Projected

Payor Source	Percent of Total
Private	0.0%
Commercial Insurance	9.8%
Medicare	17.6%
Medicaid	6.9%

Medicare/Medicaid	30.4%
Medicare/Commercial	30.4%
State Kidney Program	0.0%
VA	4.9%
Other: Self Pay/Indigent	0.0%
Total	100.0%

According to the Centers for Medicare and Medicaid Services (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 a secondary payer. Also, the CMS website states:

“Although the ESRD population in 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 2011 USRDS Annual Data Report shows the following statistics for FY 2009 in Network 6, which includes North Carolina, South Carolina, and Georgia:

**Percent of Dialysis Patients by Race/
 Ethnicity**

RACIAL GROUP	% OF DIALYSIS POPULATION
White/Caucasian	30.5%
African American	67.2%
Native American	0.6%
Asian	1.1%
Hispanic	2.6%

Percent of Dialysis Patients by Age

AGE GROUP	% OF DIALYSIS POPULATION
0 – 19	0.35%
20 – 44	13.4%
45 – 64	41.6%
65 – 74	22.8%
75 +	21.8%

Further data from that report also provides national statistics:

“On December 31, 2009, more than 362,000 ESRD patients were receiving hemodialysis therapy....”

“Nine in ten prevalent hemodialysis patients had some type of Medicare coverage in 2009, with 40 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 2009 reaching 10.8 and 10.2 percent for hemodialysis and peritoneal dialysis patients, respectfully.”

The applicant demonstrates that medically underserved populations currently have adequate access to services available at the DVA-RDC. Based on historic facility utilization data and information from CMS, and based on projections from the applicant, the applicant demonstrates that it provides adequate access to medically underserved populations. Therefore, the application is conforming to this criterion.

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

C

In application Section VI.1 (f), page 29, the applicant states:

“Roxboro Dialysis Center has no obligation under any applicable federal regulation to provide uncompensated care, community services 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 47, 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 application Section VI.1 (c), page 29, the applicant provides projected Payor mix for the services to be provided. The applicant projects no change from the current Payor mix for dialysis visits as stated in Criterion (13a) above. The applicant reports approximately 60% of patients [17.6% Medicare, 6.9% Medicaid, 30.4% Medicare/Medicaid, and 4.9% VA = 59.8%] that receive treatments at DVA-RDC Person County have some or all of their services paid for by Medicare, Medicaid or other government sources. The applicant demonstrates that medically underserved patients will have adequate access to proposed services.

Therefore, the application is conforming with 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 30, the applicant states the following:

“Patients with End Stage Renal Disease have access to dialysis services upon referral to a Nephrologist with privileges at Roxboro Dialysis Center. These referrals most commonly come from primary care physicians or specialty physicians in Person or Durham counties or transfer referrals from other nephrologists outside of the immediate area. ...Patients from outside the Roxboro Dialysis Center catchment area requesting transfer to this facility are processed in accordance with the Roxboro Dialysis Center transfer and transient policies.”
[Reference Exhibit 9]

The applicant adequately demonstrates that it will provide a range of means by which a person can access the DVA-RDC services. Therefore, the application is conforming 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 application Section V.3 (a), page 26, the applicant states:

“The Roxboro Dialysis Center is utilized as a clinical training site for area nursing schools as well as a clinical site for social work and dietary students at Duke.”

The information provided in application Section V 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

See Sections II, III, V, VI and VII. In particular, see Section II, pages 10-16, in which DVA-RDC discusses the impact of the project as it relates to promoting cost-effectiveness, quality and access. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the DVA-RDC relocation will have a positive impact on cost-effectiveness, quality and access to the proposed services for the following reasons:

- The DVA-RDC relocation is minimal and will not have a negative impact either financially or in terms of access. The relocation is a cost effective alternative to meet the need to enhance access and position the facility for near-term growth in dialysis stations;
- The applicant has and will continue to provide quality services; and
- The applicant has and will continue to provide adequate access to medically underserved populations.

Therefore, the application is conforming to this criterion, as conditioned.

- (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 DaVita Healthcare Renal Care, INC d/b/a Roxboro Dialysis Center. According to files in the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, the facility operated in compliance with the Medicare Conditions of Participation and there were no incidents resulting in a determination of immediate jeopardy during the eighteen months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

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

.2202 INFORMATION REQUIRED OF APPLICANT

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

.2202(a)(1) Utilization rates;

-C- See Section II, 1, page 10, Exhibit 7 and Section IV 1. page 22 and Section III 7, page 19-20.

.2202(a)(2) Mortality rates;

-C- See Section IV.2, page 22, Column 5

.2202(a)(3) The number of patients that are home trained and the number of patients on home dialysis;

-C- See Section IV.3, page 22.

.2202(a)(4) The number of transplants performed or referred;

-C- See Section IV.4, page 23.

.2202(a)(5) The number of patients currently on the transplant waiting list;

-C- See Section IV.5, page 23.

.2202(a)(6) Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;

-C- See Section IV.6, page 23.

.2202(a)(7) The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during the last calendar year.

-C- See Section IV.7, page 23.

(b) *An applicant that proposed develop a new facility, to 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:*

- .2202(b)(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- DVA-RDC Person County is an existing facility.
- .2202(b)(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- DVA-RDC Person County is an existing facility.
- .2202(b)(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*
-C- Reference Section XI, 6, (d), (e) and (f) and Exhibits 8 & 19.
- .2202(b)(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*
-C- See Section XI.6 (f), page 52 and Exhibits 8 & 9 regarding back-up capabilities.
- .2202(b)(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- Existing facility relocating on same site.

- .2202(b)(6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, and other relevant health and safety requirements.*
-C- See Section IV.1 through 7, pages 22 and 23.
- .2202(b)(7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*
-C- See Section III.7, pages 19-20, and Table in Criterion (3).
- .2202(b)(8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*
-NA- The new facility will be built adjacent to the existing facility.
- .2202(b)(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- See Section II.3, pages 15-16.

.2203 PERFORMANCE STANDARDS

- .2203(a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per 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- DVA-RDC is an existing facility.
- .2203(b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*
-NA- This is an existing facility of 30 dialysis stations inclusive of an isolation station. No additional stations will be added as a result of this project.
- .2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
-
NA-

.2204 SCOPE OF SERVICES

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

- .2204(1) Diagnostic and evaluation services;*
-C- See Section V.1, page 24.
- .2204(2) Maintenance dialysis;*
-C- See Section V.1, page 24.
- .2204(3) Accessible self-care training;*
-C- See Section V, 2 (d), page 25.
- .2204(4) Accessible follow-up program for support of patients dialyzing at home;*
-C- See Section V.2 (d), page 25.
- .2204(5) X-ray services;*
-C- See Section V.1, (g) page 24.
- .2204(6) Laboratory services;*
-C- See Section V.2 (a) page 25.
- .2204(7) Blood bank services;*
-C- See Section V.1, (i) page 24.
- .2204(8) Emergency care;*
-C- See Section V.1, (b) page 24
- .2204(9) Acute dialysis in an acute care setting;*
-C- See Section V.1, (a) page 24.
- .2204(10) Vascular surgery for dialysis treatment patients;*
-C- See Section V.1 (p), page 24.
- .2204(11) Transplantation services;*
-C- See Section V.1, (f) page 24.
- .2204(12) Vocational rehabilitation counseling and services; and*
-C- See Section V.1, (o) page 24.
- .2204(13) Transportation*
-C- See Section V.1, (q) page 24.

.2205 STAFFING AND STAFF TRAINING

.2205(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 494 (formerly 405.2100)*

-C- See Section VII.1 and VII.2, pages 32-35.

.2205(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- See Section VII.5, page 34 and Exhibit 12.