

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: February 1, 2013

PROJECT ANALYST: F. Gene DePorter

ASSISTANT CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: K-10041-12/ DaVita Healthcare Renal Care, Inc. d/b/a Roxboro Dialysis Center / Add 5 dialysis stations for a total of 35 stations upon completion of this project, Project I.D. #K-8573-10 (add 6 stations) and Project K-8818-12 (relocate facility) / Person

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 proposes to add five dialysis stations to Roxboro Dialysis Center following relocation of the facility within Roxboro and the addition of 6 six stations (Project # K-8573-10) for a total of 35 dialysis stations.

The 2012 State Medical Facilities Plan (2012 SMFP) provides a county need methodology and a facility need methodology for determining the need for additional dialysis stations. According to the July 2012 Semiannual Dialysis Report (SDR), the county need methodology shows there is no need for an additional facility in Person County. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate reported for Roxboro Dialysis Center in the July 2012 SDR is 4.21 patients per station and the utilization percentage is 105.21%. This utilization rate was calculated based on 101 in-center dialysis patients and 24 certified dialysis stations as of

12/31/2011 [101 patients / 24 stations = 4.21 patients per station; 4.21 patients per station / 4 patients per station = 105.21%]. Therefore, application of the facility need methodology indicates additional stations are needed for this facility, as illustrated in the following table.

Table 1

Required SDR Utilization		80%
Center Utilization Rate as of 12/31/11		105.2%
Certified Stations		24
Pending Stations		6
Total Existing and Pending Stations		30
In-Center Patients as of 12/31/11 (SDR 2)		101
In-Center Patients as of 6/30/11 (SDR 1)		89
Step	Description	Result
(i)	Difference (SDR2 – SDR1)	12
	Multiply the difference by 2 for the projected net in-center change	24
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/11	0.2697
(ii)	Divide the result of step (i) by 12	0.0225
(iii)	Multiply the result of step (ii) by the number of months from 12/31/10 until the end of calendar year 2011 (12 months)	0.2697
(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	128.2360
(v)	Divide the result of step (iv) by 3.2 patients per station	40.0737
	and subtract the number of certified and pending stations as recorded in SDR2 [30] to determine the number of stations needed	10

Step (C) of the facility need methodology states; *“The facility may apply to expand to meet the need established... up to a maximum of 10 stations.”* As shown in the table above, based on the facility need methodology for dialysis stations, the number of stations needed is ten. The applicant proposes to add only five stations. The application is consistent with the facility need determination

Policy GEN-3 in the 2012 SMFP is applicable to this review. Policy GEN-3 states:

“A CON 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 (SMFP) 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 CON 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 CON applicant shall also document how its projected

volumes incorporate these concepts in meeting the need identified in the SMFP as well as addressing the needs of all residents in the proposed service area.”

Promote Safety and Quality

On page 16, the applicant states the following regarding the methods employed to promote safety and quality:

“DaVita Inc. is committed to providing quality care to the ESRD population through a comprehensive Quality Management Program. DaVita’s Quality Management Program is facilitated by a dedicated clinical team of RN and Biomedical Quality Management Coordinators working under the direction of our Director of Quality Management and Director of Integrated Quality Development. These efforts receive the full support and guidance of the clinical executive leadership team of DaVita. Combined, this group brings hundreds of years of ESDR experience to the program. The program exemplifies DaVita’s total commitment to enhancing the quality of patient care through its willingness to devote the necessary resources to achieve our clinical goals. Our Quality Management Program includes the following quality programs:

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

The applicant adequately demonstrates how its proposal will promote safety and quality.

Promote Equitable Access

On pages 29-32, the applicant provides information about accessibility to its services. The applicant states:

“Roxboro Dialysis Center, 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.”

In 2011, 85.3% of Roxboro Dialysis Center services were provided to Medicare and Medicaid recipients.

The applicant adequately demonstrates how its proposal will promote access to medically underserved groups.

Maximize Healthcare Value

The applicant states that the proposed project does not include any new construction. On page 42, the applicant states there are no start-up expenses or initial operating expenses associated with this project. In Section XI, page 52, the applicant describes the methods that will be used for energy efficiency and operating cost containment. The applicant adequately demonstrates how its proposal will maximize healthcare value. Additionally, the applicant adequately demonstrates projected volumes for the proposed services incorporate the basic principles in meeting the needs of patients to be served.

The application is consistent with the facility need determination in the 2012 SMFP and Policy GEN-3. Therefore, the application is conforming to this criteria.

- (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

Roxboro Dialysis Center proposes to add 5 dialysis stations for a total of 35 stations upon completion of this project, Project ID # K-8573-10 (add 6 stations) and Project I.D. # K-8812-12 (relocate facility).

Population to be Served

In 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 shown in the following tables.

Table 2
Roxboro Dialysis Center Historic Patient Origin

County	CY 2010		CY 2011		CY 2012	
	In-Center	Home	In-Center	Home	In-Center	Home
Person	84	6	89	6	86	6
Caswell	7	0	8	0	7	0
Durham	3	0	3	0	3	0
Orange	1	0	1	0	1	0
Alamance	1	0	1	0	1	0
Virginia	1	0	1	0	1	0
Total	98	6	101	6	100	6

Source: Section III.7, page 22.

Table 3
Roxboro Dialysis Center Projected Patient Origin

County	CY 2013		YR 1 CY 2014		YR 2 CY 2015		County Patients As a Percent of Total	
	In-Center	Home	In-Center	Home	In-Center	Home	Year 1	Year 2
Person	88	6	101	0	106	0	87.8%	88.3%
Caswell	7	0	8	0	8	0	7.0%	6.7%
Durham	3	0	3	0	3	0	2.6%	2.5%
Orange	1	0	1	0	1	0	0.86%	0.83%
Alamance	1	0	1	0	1	0	0.86%	0.83%
Virginia	1	0	1	0	1	0	0.86%	0.83%
Total	101	6	115	0	120	0	100%	100%

Source: Section III.7, page 20.

The applicant adequately identifies the population to be served.

Demonstration of Need

In Section III.7, page 20, the applicant provides the assumptions and methodology used to project utilization, as follows:

- “1) The Roxboro Dialysis Center had 101 in-center patients as of December 31, 2011 based on information included in Table A of the July 2012 Semiannual Dialysis Report (SDR). This is a station utilization rate of 84% based on the 30 certified and approved stations in the facility. Of the 101 in-patients cited in the SDR, 89 patients will live in Person County, 8 of the patients lived in Caswell County, 3 patients lived in Durham County, one patient lived in Alamance County, one patient lived in Orange County and one patient lived in South Boston, Virginia.
- 2) The July 2012 SDR indicates in Table B that Person County has experienced an annual average change rate of 4.5% for the past five years.
- 3) We have grown the patient population of the Roxboro Dialysis Center patients beginning July 1, 2012 through the projected operating year 2 [2015]. The calculations below

begin with 89 in-center patients living in Person County in operating year 2012 and modified in each subsequent year by the Average Annual Rate of Growth of 4.5% :

July 1, 2012-December 31, 2012 – 89 patients X 1.045 = 93.005

January 1, 2013- December 31, 2013- 93.005 patients X 1.045 = 97.190225

January 1, 2014- December 31, 2014- 97.190225 patients X 1.045= 101.5637851

January 15, 2015- December 31, 2015- 101.5637851 patients X 1.045= 106.1341554

- 4) *At the end of operating year one [1/1/14 through 12/31/14] the Roxboro Dialysis Center is projected to have an in-center patient census of 115 patients.*
- 5) *At the end of operating year two [1/1/15 through 12/31/15] the Roxboro Dialysis Center is projected to have an in-center patient census of 120 patients.”*

Roxboro Dialysis Center is projected to have a utilization rate of 82.1% or 3.3 patients per station based on 115 in-center patients by the end of operating year one and a utilization rate of 85.7% and 3.4 patients per station based on 120 in-center patients by end of operating year two. Thus, the applicant projects to serve at least 3.2 patients per station per week by the end of operating year one, which is consistent with the requirement in 10A NCAC 14C. 2203(b). Projected utilization in the first two operating years is based on reasonable, credible and supported assumptions regarding continued growth.

In summary, the applicant adequately identified the population to be served and demonstrated the need for five additional dialysis stations dialysis stations based on the population it proposes to serve. Therefore, the application is conforming to this criterion.

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

NA

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

CA

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

“There were only two alternatives for meeting the needs of the proposed project considered. The first was to do nothing. The second was to apply for a five station expansion of the facility when it is relocated. We chose to expand the facility since the ESRD patient population continues to grow.”

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that its proposal is the least costly or most effective alternative to meet the need. Therefore, the application is conforming to this 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 the certificate of need application.**
 2. **DaVita Healthcare Renal Care, Inc. d/b/a Roxboro Dialysis Center shall develop and operate no more than 5 additional dialysis stations for a total of no more than 35 certified stations upon completion of this project, Project ID # K-8573-12 (add 6 stations) and Project ID # K-8818-12 (relocate facility) including any isolation or home hemodialysis stations.**
 3. **DaVita Healthcare Renal Care, Inc. d/b/a Roxboro Dialysis Center shall install plumbing and electrical wiring through the walls for no more than 35 dialysis stations at the replacement facility.**
 4. **DVA Healthcare Renal Care, Inc. d/b/a Roxboro Dialysis Center, shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

In Section VIII.1, pages 36-37, the applicant projects that the total capital cost of the project will be \$77,000, as shown in the table below.

Table 4

Dialysis Machines	\$ 59,275
Dialysis Chairs	\$ 23,080
(RO) Water Treatment Equipment	\$ 2,500

Other Equip & Furniture	\$ 2,000
Dialysis Chairs	\$ 4,850
Televisions	\$ 5,975
Chair side Computer Terminals	\$ 2,400
Total	\$77,000

In Section IX.3, page 41, the applicant states that there are no start-up or initial operating expenses associated with this project. In Section VIII, page 38, the applicant states that DaVita, Inc. will fund this project from cash reserves. Exhibit 13 contains a letter, dated September 14, 2012, from the Chief Accounting Officer for DaVita, Inc. which states:

“I am the Chief Accounting Officer of DaVita, Inc., the parent and owner of DVA Healthcare Renal Care, Inc. We are submitting a Certificate of Need application to expand our Roxboro Dialysis Center by five ESRD dialysis stations.

The project calls for a capital expenditure of \$77,000. This letter will confirm that DaVita, Inc has committed cash reserves in the total sum of \$77,000 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 needs of the project.

In Section X.1, page 43, the applicant provides the projected allowable charges per treatment for each payment source, as follows:

Table 5

SOURCE OF PAYMENT	CHARGE PER TREATMENT
Medicare	\$192.00
Medicaid	\$192.00
Medicare/Medicaid	\$240.00
Commercial Insurance	\$800.00
VA	\$240.00
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 Section X.4, page 46, the applicant provides projected revenues and expenses, as follows:

Table 6
Roxboro Dialysis Center

	OPERATING YEAR 1 (7/1/2013 –6/30/2014)	OPERATING YEAR 2 (7/1/2014 –6/30/2015)
Net Revenue	\$4,741,296	\$4,930,512

Total Operating Expenses	\$4,388,668	\$4,503,388
Net Profit	\$ 352,628	\$ 427,124

Roxboro Dialysis Center projects that revenue will exceed operating expenses in each of the first two operating years. The assumptions used in preparation of the pro formas, including the number of projected treatments, are reasonable, credible and supported. See Section X, pages 44-46, for the applicant’s assumptions.

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.

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The Roxboro Dialysis Center proposes to add five dialysis stations to the existing facility for a total of 35 stations upon completion of the proposed project. Based on the facility need methodology in the 2012 SMFP, the applicant adequately demonstrates the need for five additional stations based on the number of in-center patients it proposes to serve. As of December 25, 2012, the 24 station facility was operating at 105.21% ($101 / 24 = 4.2083$; $4.2 / 4 = 1.05\%$). Upon completion of this project, the facility will have 35 stations with 115 patients (end of the first full year) for 3.29 patients per station and an occupancy rate of 82.25% ($115 / 35 = 3.29$; $3.29 / 4 = 82.25\%$). Projected utilization is based on reasonable, credible and supported assumptions regarding continue growth.

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

- (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 33, the applicant provides the current and projected staffing for Roxboro Dialysis Center, as shown in the following table:

Table 7

	Current FTE Positions	Projected FTE Positions
RN	3.5	5.0

HTRN	0.5	0.5
PCT	13.0	15.0
Bio-Med Tech.	0.5	1.0
Administrator	1.0	1.0
Dietitian	0.7	1.0
Social Worker	0.7	1.0
Clerical	1.0	1.5
Total	20.9	26.0

The applicant indicates in Section VII.2, page 33, that the facility complies with all staffing requirements in 42 C.F.R. Section 405.2100. The applicant further states in Section VII.4, page 34, that it does not expect any difficulty in recruiting staff. The information regarding staffing provided in Section VII is reasonable and credible. The Medical Director of the facility is Dr. Eugene Kovalik who is a board certified nephrologist. The applicant adequately documents the availability of resources, including a medical director, for the provision of dialysis services. Therefore, the application is conforming to this criterion.

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

C

In Section V.1, page 25, the applicant lists the providers of the necessary ancillary and support services. In Section V.4 (b), page 27, the applicant provides a list of physicians who have expressed support for the project and a willingness to provide medical coverage. 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 care 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 (HMO) 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(a), page 29, 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 underserved persons.”

In Section VI.1(d), page 30, 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 30, the applicant reports the current payer mix for Roxboro Dialysis Center as shown in the following table.

**Table 8
 Roxboro Dialysis Center
 Historic Payor Mix**

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%

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.

Table 9

County	June 2010 Total # of Medicaid Eligible as % of Total Population	June 2010 Total # of Medicaid Eligible Age 21 and older as % of Total Population	% Uninsured CY 08-09 (Estimate by Cecil G. Sheps Center)
Person	18.2%	8.7%	18.0%
Statewide	16.5%	7.3%	19.7%

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

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by Roxboro Dialysis Center. 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 are available by age, race or gender. However, a direct comparison to the applicant’s 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.

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 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... .”

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 in 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, respectfully.”

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

Table 10

ESRD Spending by Payor		
Payor	Spending in Billions	% of Total Spending
Medicare Paid	\$29.6	62.32%
Medicare Patient Obligation	\$4.7	9.89%

Medicare HMO	\$3.4	7.16%
Non-Medicare	\$9.8	20.63%

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

Table 11

Number and Percent of Dialysis Patients by Age, Race and Gender		
	# of ESRD Patients	% of Dialysis Population
AGE		
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%
Gender		
Female	4,237	45.3%
Male	5,105	54.65%
Race		
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 provided at Roxboro Dialysis Center. 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

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.1(f), page 30, 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 32, the applicant states, “*There has 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 VI.1(c), page 30, the applicant provides the projected payor mix for the proposed services. The applicant projects no change from the current payor mix which is 78.4% Medicare and 6.9% Medicaid, which represents 85.3% of all patients served. The applicant demonstrates that medically underserved patients will have adequate access to proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section VI.5 (a), page 31, the applicant states 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.”

The applicant adequately demonstrates that it will provide a range of means by which a person can access the proposed services. Therefore, the application is conforming 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(a), page 27, 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

Roxboro Dialysis Center proposes to add five stations for a total of 35 stations upon completion of this project, Project ID # K-8573-10 (add six stations) and Project ID# K-8818-12 (relocate 24 station facility). Roxboro Dialysis Center is the only ESRD provider in Person County.

In Section V, pages 25-28, the applicant discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and access. See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost effectiveness, quality and access.

The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the expected effects of the proposal on competition in the service area include a positive impact on cost-effectiveness, quality and access. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need to add five dialysis stations pursuant to the facility need methodology and that it is a cost-effective alternative to meet that need.
- The applicant will continue to provide quality services; and
- The applicant will continue to provide adequate access to medically underserved populations.

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

According to files in the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, Roxboro Dialysis Center operated in compliance with the Medicare Conditions of Participation and that 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 appropriate 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 regulatory review criteria. The specific criteria are discussed below.

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANTS

(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 Exhibit 7.

The July 2012 SDR utilization rate was 105.21% as of December 31, 2011.

.2202(a)(2) Mortality rates;

-C- The mortality rate was 12.1% in 2011. See Section IV. 2, page 23.

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

-C- Roxboro Dialysis Center is not serving home-trained patients at this time. The facility is certified for home training. See Section IV.3, page 23.

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

-C- In 2011, 16 patients were referred for transplant evaluation and 2 patients received transplants. See Section IV.4, page 24.

- .2202(a)(5) *The number of patients currently on the transplant waiting list;*
-C- In Section IV.5, page 24, the applicant states there are 12 patients on the transplant waiting list.
- .2202(a)(6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*
-C- In Section IV.6, page 24, the applicant provides the following information:
Dialysis related hospital admissions 22
Non-dialysis related hospital admissions 190
Percent Dialysis Related 10.4%
Percent Non-dialysis Related 89.6%
Total number of hospital admissions 212
- .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- As of December 31, 2011, there were no patients dialyzing in the Roxboro Dialysis Center with AIDS and no patients with Hepatitis B. No patients treated with infectious disease have converted to infectious status since 2011. See Section IV.7, page 24.

(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- The Roxboro Dialysis Center 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 transplant, and*
(E) *Signatures of the duly authorized persons representing the facilities and the agency providing services.*
-NA- Roxboro Dialysis Center is an existing facility.
- .2202(b)(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*
-NA- Roxboro Dialysis Center is an existing facility.

- .2202(b)(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*
-C- Exhibit 8 contains a copy of the policy and procedure for back-up of electrical service in the event of a power outage.
- .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- Roxboro Dialysis Center is an existing facility.
- .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 XI.6(g) pages 52-53, and Exhibits 1, 18 and 19.
- .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 20-21, for the assumptions and methodology. See Criterion (3) for discussion which is incorporated hereby as if set forth fully herein.
- .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- Roxboro Dialysis Center is an existing facility. The applicant was approved in an earlier application to relocate the facility. That application was determined to be conforming to this Rule.
- .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- In Section II.1, page 12, the applicant states that it will admit and provide dialysis services to patients who have no insurance or other source of payment, if payment for dialysis is made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.

10 NCAC 14C .2203 PERFORMANCE STANDARDS

.2203(a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per 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- Roxboro Dialysis Center 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.*

-C- On page 21, the applicant projects to serve 115 in-center patients by the end of Year One which is 3.3 patients per station ($115 / 35 = 3.29$). See Criterion (3) for discussion which is incorporated hereby as if set forth fully herein.

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

-C- On pages 12-14, and 20-21, the applicant provides the assumptions and methodology used. See Criterion (3) for discussion which is incorporated hereby as if set forth fully herein.

10 NCAC 14C .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- These services will be provided by Duke University Medical Center. See Section V.1, page 25.

.2204(2) *Maintenance dialysis;*

-C- These services are provided by Roxboro Dialysis Center staff. See Section V.1, Page 25.

.2204(3) *Accessible self-care training;*

-C- These services are provided by Roxboro Dialysis Center. See Section V.1, page 25, and Section IV.3, page 23.

.2204(4) *Accessible follow-up program for support of patients dialyzing at home;*

-C- See Section V.1, page 25. These services are provided by Roxboro Dialysis Center.

.2204(5) *X-ray services;*

-C- See Section V.1, page 25. X-ray services are provided by Duke University Medical Center.

.2204(6) *Laboratory services;*

-C- See Section V.1, page 25. Both routine and special laboratory

services are provided by Dialysis Laboratories.

- .2204(7) *Blood bank services;*
-C- See Section V.1, page 25. Blood bank services are provided by Duke University Medical Center.
- .2204(8) *Emergency care;*
-C- See Section V.1, page 25. Emergency care is available at Duke University Medical Center.
- .2204(9) *Acute dialysis in an acute care setting;*
-C- See Section V.1, page 25. Acute dialysis in an acute setting is available at Duke University Medical Center.
- .2204(10) *Vascular surgery for dialysis treatment patients;*
-C- See Section V.1, page 25. Vascular surgery services are available at Duke University Medical Center.
- .2204(11) *Transplantation services;*
-C- See Section V.1, page 25. Transplantation services are available at Duke University Medical Center.
- .2204(12) *Vocational rehabilitation counseling and services; and*
-C- See Section V.1, page 25. Service is provided by the North Carolina Division of Vocational Rehabilitation Services.
- .2204(13) *Transportation*
-C- See Section V.1, page 25. Transportation is provided by DSS.

.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 405.2100*
-C- See Section VII.,1, pages 33-36 for the proposed staffing. On page 33, the applicant states proposed staffing conforms with 42 CFR 494 (formerly 42 CFR 405.2100).
- .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 35, and Exhibit 12.