

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: January 29, 2013

PROJECT ANALYST: Jane Rhoe-Jones
ASSISTANT CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: P-10037-12 / Total Renal Care of North Carolina, LLC d/b/a Greene County Dialysis Center / Add five dialysis stations to the existing facility for a total of 21 certified stations upon project completion / Greene County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Total Renal Care of North Carolina, LLC d/b/a Greene County Dialysis Center currently operates a 16-station dialysis facility located at 1025 Kingold Boulevard in Snow Hill, North Carolina, 28580. The applicant proposes to add five dialysis stations to the existing facility for a total of 21 stations upon project completion.

The 2012 State Medical Facilities Plan (2012 SMFP) provides a county need methodology and a facility need methodology for determining the need for new 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 Greene County. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology. The utilization rate reported for Greene County Dialysis Center in the July 2012 SDR is 3.43 patients per station, or 85.9%. This utilization rate was calculated based on 55 in-center dialysis patients and 16 certified dialysis stations as of December 31, 2011 (55 patients / 16 stations = 3.43 patients per station; 3.43 patients per station / 4.00 patients per station = 85.9%). Therefore, application of the facility need

methodology indicates additional stations are needed for this facility, as illustrated in the following table:

Green County Dialysis Center October 2012 Review		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/2011		85.9%
Certified Stations		16
Pending Stations		0
Total Existing and Pending Stations		16
In-Center Patients as of 12/31/2011 (SDR2)		55
In-Center Patients as of 6/30/2011 (SDR1)		47
Step	Description	
(i)	Difference (SDR2 - SDR1)	8
	Multiply the difference by 2 for the projected net in-center change	16
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 06/30/11	0.3404
(ii)	Divide the result of Step (i) by 12	0.0284
(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)	0.3404
(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	73.7234
(v)	Divide the result of Step (iv) by 3.2 patients per station	23.0386
	and subtract the number of certified and pending stations as recorded in SDR2 [16 stations] to determine the number of stations needed	7

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

Policy GEN-3 in the 2012 SMFP is also 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

The applicant discusses its quality index in Section I, pages 7-8. Also, in Section II.3, pages 16-17, the applicant states,

“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.

... 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.

Greene County Dialysis Center is attended by Dr. William Bynum, Eastern Nephrology Associates and Dr. Richard Merrill, admitting Nephrologists who directly oversee the quality of care of the dialysis facility. In addition, Dr. Bynum serves as Medical Director and provides the overall medical supervision of the dialysis unit. The facility unit administrator is the day to day manager of the facility and maintains the DaVita Quality Management Program that monitors the overall care of the patients. The Quality Management Program is reviewed by the Quality Assurance Committee consisting of the Nephrologists, Unit Administrator, clinical teammates, social worker and the dietitian. ... Continuous Quality Improvement teams address facility issues with the goal of improving patient care patient outcomes.”

The applicant also discusses its safety measures in Section XI.6(g), pages 54-55. In Exhibit 4 the applicant provides published articles about its clinical outcomes and a copy of an article which describes DaVita’s quality index. In Exhibit 10, the applicant provides a copy of its isolation policies and procedures and in Exhibit 18, the applicant provides a copy of its safety training outline. The applicant adequately demonstrates how its proposal will promote safety and quality in the provision of dialysis services in Greene County.

Promote Equitable Access

In Section VI, pages 30-33, the applicant provides information about accessibility to its services. On page 30, the applicant states,

“Greene County 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, or handicap or ethnic and socioeconomic groups of patients in need of dialysis regardless of their ability to pay.

Greene County 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. Greene County Dialysis Center provides dialysis six days per week with two patient shifts per day to accommodate patient need.

Greene County 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. Greene County Dialysis Center works with patients who need transportation, when necessary.”

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

Maximize Healthcare Value

In Section III.9, pages 21-22, the applicant states,

“Greene County Dialysis Center promotes cost-effective approaches in the facility in the following ways:

- *... 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. We will be purchasing the equipment for this project under this procedure.*
- *Greene County Dialysis Center purchases all of the products utilized in the facility, from office supplies to drugs to clinical supplies, under a national contract in order to secure the best products at the best price.*
- *Greene County Dialysis Center utilizes the reuse process that contains costs and the amount of dialyzer waste generated by the facility.*
- *Greene County Dialysis Center has installed an electronic patient charting system that reduces the need for paper in the facility. Much of the other documentation in the facility is also done on computer which reduces the need for paper.*
- *Greene County Dialysis Center Bio-Medical Technician assigned to the facility conducts preventative maintenance on the dialysis machines on a monthly, quarterly, and semi-annual schedule that reduces the need for repair maintenance and parts. This extends the life of the dialysis machines.*
- *Greene County Dialysis Center also has an inventory control plan that ensures enough supplies are available without having an inordinate amount of supplies on hand. Supply orders are done in a timely manner to ensure that the facility does not run out of supplies, thus avoiding emergency ordering, which is costly.”*

The applicant adequately demonstrates how its proposal will maximize healthcare value. Additionally, the applicant 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 Policy GEN-3.

- The application is conforming to this criterion.
- (2) Repealed effective July 1, 1987.
 - (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

Total Renal Care of North Carolina, LLC d/b/a Greene County Dialysis Center currently operates a 16-station dialysis facility located at 1025 Kingold Boulevard in Snow Hill, North Carolina, 28580. The applicant proposes to add five dialysis stations to the existing facility for a total of 21 stations upon project completion. The July 2012 SDR indicates a total of 16 certified stations at the Greene County Dialysis Center, as of January 31, 2012. Based on patient origin information provided in the table in Section III.7, page 20 of the application, the applicant does not propose any home training.

Population to be Served

In Section IV.1, page 23, the applicant states that the number of in-center patients served at Greene County Dialysis Center as of December 31, 2011 is as follows:

Greene County Dialysis Center	
COUNTY OF RESIDENCE	# OF PATIENTS DIALYZING IN-CENTER
Greene	45
Lenoir	4
Pitt	4
Wilson	2
Total	55

In Section III.7, page 20, the applicant provides the projected patient origin for Greene County Dialysis Center for the first two years of operation following completion of the project as follows:

Greene County Dialysis Center						
County	Operating Year 1 2014		Operating Year 2 2015		County Patients as a Percent of Total	
	In-Center Patients	Home Dialysis Patients	In-Center Patients	Home Dialysis Patients	Year 1	Year 2
Greene	58	0	64	0	85.3%	86.5%
Lenoir	4	0	4	0	5.9%	5.4%
Pitt	4	0	4	0	5.9%	5.4%
Wilson	2	0	2	0	2.9%	2.7%
TOTAL	68	0	74	0	100%	100%

The applicant adequately identifies the population it proposes to serve.

Demonstration of Need

In Section II, pages 13-14, and in Section III.7, pages 20-21, the applicant provides the assumptions and methodology it used to project utilization at Greene County Dialysis Center. The applicant states,

- *“The facility had 55 in-center patients as of December 31, 2011 based on data reported in Table A of the July 2012 Semiannual Dialysis Report.*
- *The table in Section III.2 indicates that the facility is eligible for a five-station expansion, based on facility need methodology.*
- *The Greene County Dialysis Center had a 10.7% five year average annual change rate.*
- *... This is station utilization rate of 86% based on the 16 certified stations in the facility. Of the 55 in-center patients cited in the SDR, 45 of the patients live in Greene County, four of the patients live in Lenoir County, four patients live in Pitt County and two patients live in Wilson County.*
- *We have grown the patient population of the Greene County Dialysis Center patients beginning July 1, 2012 through the projected operating year 2.*

July 1, 2012-December 31, 2012 - 45 patients X 1.053 = 47.4075

January 1, 2013-December 31, 2013 - 47.4075 patients X 1.107 = 52.4801

January 1, 2014-December 31, 2014 - 52.4801 patients X 1.107 = 58.0954

January 1, 2015-December 31, 2015 - 58.09547 patients X 1.107 = 64.3116

July 1, 2014 – June 30, 2014 (operating year 1)

July 1, 2015 – June 30, 2015 (operating year 2)

At the end of operating year one the Greene County Dialysis Center is projected to have an in-center patient census of 68 patents (58 Green County patients, 4 Lenoir County patients, 4 Pitt County patients and 2 Wilson County patients = 68 total patients) for utilization rate of 81% or 3.2 patients per station. [68 patients / 21 stations = 3.23 patients per station; 3.23 patients per station / 4.00 patients per station = 81%]

At the end of operating year two the Greene County Dialysis Center is projected to have an in-center patient census of 74 patients (64 Greene County patients, 4 Lenoir County patients, 4 Pitt County patients and 2 Wilson County patients = 74 total patients) for utilization rate of 88% or 3.5 patients per station. We did not calculate the growth of the patients residing outside of Greene County.” [74 patients / 21

stations = 3.52 patients per station; 3.52 patients per station / 4.00 patients per station
= 88%]

Projected utilization at the end of Year One equals 3.2 in-center patients per station per week as required by 10A NCAC 14C .2203(b) and the number of in-center patients projected to be served is based on reasonable and supported assumptions regarding future growth.

Access

In Section VI, page 31, the applicant projects that 86% of the patients at Greene County Dialysis Center will be covered by Medicare and Medicaid. The applicant demonstrates adequate access for the medically underserved populations at Greene County Dialysis Center.

In summary, the applicant adequately identifies the population to be served and adequately demonstrates the need for five additional dialysis stations at the Greene County Dialysis Center. Consequently, 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.

C

In Section III.9, page 21, the applicant discusses the alternatives considered prior to the submission of this application, which include:

- 1) Maintain the Status Quo – The applicant states this is not an effective alternative because volume at Greene County Dialysis Center is growing rapidly.
- 2) Add five stations - The applicant states this is the most effective alternative to meet the growing demand for dialysis services at Greene County Dialysis Center. Table B in the July 2012 SDR indicates an average annual change rate of over 10% in Greene County. Greene County Dialysis Center is the only dialysis facility in Greene County. The applicant projects a utilization rate of 81% by the end of the first operating year and 88% by the end of the second operating year.

On page 21, the applicant states:

“There are only two alternatives of meeting the needs of the proposed project considered. The first was to do nothing. This alternative was dismissed since the facility is rapidly growing. The second was to apply for the five-station expansion. We chose the second alternative in order to help meet the growing demand for dialysis services at Greene County Dialysis Center.”

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

In summary, the applicant adequately demonstrates that the proposal to add five stations 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. Total Renal Care of North Carolina, LLC d/b/a Greene County Dialysis Center shall materially comply with all representations made in the certificate of need application.**
 - 2. Total Renal Care of North Carolina, LLC d/b/a Greene County Dialysis Center shall develop and operate no more than five additional dialysis stations for a total of no more than 21 certified stations, which shall include any isolation stations.**
 - 3. Total Renal Care of North Carolina, LLC d/b/a Greene County Dialysis Center shall install plumbing and electrical wiring through the walls for no more than five additional dialysis stations for a total of no more than 21 dialysis stations, which shall include any isolation stations.**
 - 4. Total Renal Care of North Carolina, LLC d/b/a Greene County Dialysis Center shall not offer or develop home hemodialysis or peritoneal dialysis training services as part of this project.**
 - 5. Total Renal Care of North Carolina, LLC d/b/a Greene County 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.

In Section VIII, page 38, the applicant states that the capital cost is projected to be \$469,481. In Sections IX.3, page 43, the applicant projects that there will be no start-up or initial operating expenses associated with the proposed project.

In Section X.1, page 45, the applicant projects that the allowable charges per treatment for each payment source are as follows:

SOURCE OF PAYMENT	CHARGE PER TREATMENT
Medicare	\$192.00
Medicaid	\$192.00
Medicare/Medicaid	\$240.00
Medicare/Commercial	\$240.00
VA	\$240.00
Commercial Insurance	\$800.00

The rates shown above are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services. In Section X.2-X.4, pages 46-48, the applicant reported projected revenues and expenses as follows:

	OPERATING YEAR 1	OPERATING YEAR 2
Total Net Revenue	\$2,401,312	\$2,663,344
Total Operating Costs	\$2,287,278	\$2,481,796
Net Profit	\$114,034	\$181,548

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

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital needs of this project. The applicant also adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

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

C

Total Renal Care of North Carolina, LLC d/b/a Greene County Dialysis Center proposes to add five in-center dialysis stations to the existing facility for a total of 21 dialysis stations upon project completion. Greene County Dialysis Center is currently serving 55 patients weekly at 3.43 patients per station, which is 86% of capacity. Dialysis facilities that operate four shifts per week (2 per day on alternate days) have a capacity of four patients per station. The applicant does not propose to establish a new facility. The applicant discusses projections for the in-center patient population on pages 13-14 and 20-21 of the application. At the end of Operating Year Two, with 21 dialysis stations and 74 dialysis patients after the

five-station addition, the applicant projects utilization will be 3.5 in-center patients per station (74 patients / 21 dialysis stations = 3.52). The growth projections are based on Greene County projected Average Annual Growth Rate in the number of dialysis patients. Greene County Dialysis Center is the only dialysis facility in Greene County.

The applicant adequately demonstrates the need to add five dialysis stations to the existing facility based on the number of in-center patients it proposes to serve. 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 applicant is conforming to this criterion.

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

C

Section VII.1, page 34, the applicant provides current and projected staffing for Greene County Dialysis Center as illustrated in the following table:

GREENE COUNTY DIALYSIS CENTER			
POSITION	CURRENT FTES	PROJECTED # OF NEW FTES	TOTAL # FTES
RN	2	1	3
PCT	6	3	9
Bio-Med Tech	.5	.2	.7
MD			
Admin	1	0	1
Dietician	.5	.2	.7
Social Worker	.5	.2	.7
Unit Secretary	1	0	1
Other-Reuse	.5	.5	1
Total	12.0	5.1	17.1

As shown in the above table, the applicant proposes to employ a total of 17.1 full-time equivalent (FTE) positions to staff the Greene County Dialysis Center upon completion of the proposed project. In Section V.4, page 27, the applicant states that William Bynum, MD is currently the medical director of the facility. In Section VII.2, page 35, the applicant states Dr. Bynum is Board-Certified in Nephrology.

The information regarding staffing provided in Section VII is reasonable and credible. The applicant adequately demonstrates the availability of adequate health manpower and management personnel, 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, pages 25-26, the applicant lists the providers of the necessary ancillary and support services. The applicant identifies the method for providing the services on pages 14-15 of the application. Acute hospital care, diagnostic evaluation services, X-ray services, blood bank services and emergency care beyond facility capability will be provided by Wilson Medical Center, Lenoir Memorial Hospital and Vidant Medical Center-Greenville. Dialysis maintenance, psychological and nutritional counseling, social services and isolation will be provided by Greene County Dialysis Center on site. Other services will be provided by stated providers.

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.

NA

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

C

In Section VI.1(b), page 30, the applicant reports that 85.7% of the patients who received treatments at Greene County Dialysis Center had some or all of their services paid for by Medicare or Medicaid in the past year. The table below illustrates the historical payor mix for the facility:

Greene County Dialysis Center	
Source of Payment	Percentage
Medicare/Medicaid	32.2%
Medicare/Commercial	21.4%
Medicare	21.4%
Commercial Insurance	12.5%
Medicaid	10.7%
VA	1.8%
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. The following table illustrates those percentages for Greene County and statewide.

	CY 2009 Total # of Medicaid Eligibles as % of Total Population *	CY 2009 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	CY 2009 % Uninsured (Estimate by Cecil G. Sheps Center)*
Greene County	17%	6.7%	19.7%

Statewide	21%	7.6%	24.6%
-----------	-----	------	-------

*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 the Greene County Dialysis Center facility. In fact, only 5.8% of all 2011 ESRD patients in North Carolina's Network 6 were under the age of 35.

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

The Centers for Medicare & Medicaid Services (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.”^[1]

Additionally, the United States Renal Data System, in its 2012 USRDS Annual Data Report (page 225) provides these national statistics for FY 2010:

“On December 31, 2010, more than 376,000 ESRD patients were receiving hemodialysis therapy.”

Of the 376,000 ESRD patients, 38.23% were African American, 55.38% were white, 55.65% were male and 44.65% were 65 and older. The report further states:

“Nine of ten prevalent hemodialysis patients had some type of Medicare coverage in 2010, with 39 percent covered solely by Medicare, and 32 percent covered by Medicare/Medicaid. ... Coverage by non-Medicare insurers

continues to increase in the dialysis population, in 2010 reaching 10.7 and 10.0 percent for hemodialysis and peritoneal dialysis patients, respectively.”

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

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%

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

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

Number and Percent of Dialysis Patients by Age, Race and Gender		
	# of ESRD Patients	% of Dialysis Population
Ages		
0-19	89	1.0%
20-34	451	4.8%
35-44	773	8.3%
45-54	1,529	16.4%
55-64	2,370	25.4%
65-74	2,258	24.2%
75+	1,872	20.0%
Gender		
Female	4,237	45.35%
Male	5,105	54.65%
Race		
African American	5,096	54.55%
White/Caucasian	4,027	43.11%
Other	219	2.3%

Source: Southeastern Kidney Council (SKC) Network 6. Includes North Carolina, South Carolina and Georgia

[1](www.cms.gov/medicare/end-stage-renal-disease/esrdnetworkorganizations/downloads/esrdnetworkprogrambackgroundpublic.pdf)

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 Section VI.6 (a), page 33, the applicant states there have been no civil rights access complaints filed within the last five years. Therefore, the application is conforming to this criterion.

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

C

In Section VI.1(c), page 31, the applicant provides the projected payor mix for the proposed services at Greene County Dialysis Center. The applicant projects no change from the current payor mix for dialysis visits which is 75% Medicare and 10.7% Medicaid, which equals 85.7% of all patients served. The applicant demonstrates that medically underserved populations would have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section VI.5, page 32, the applicant states,

*“Patients with End Stage Renal Disease have access to dialysis services upon referral to a Nephrologist with privileges at Greene County Dialysis Center. These referrals most commonly come from primary care physicians or specialty physicians in Greene County. Patients, families and friends can obtain access by contacting a Nephrologist with privileges at the facility. Should a patient contact Greene County Dialysis Center directly or indirectly, the patient is referred to a qualified Nephrologist for evaluation and subsequent admission if medically necessary. Patients from outside the Greene County Dialysis Center catchment area requesting transfer to this facility are processed in accordance with the Greene County Dialysis Center transfer and transient policies which comprise **Exhibit 9**. The patient, again, is referred to a qualified Nephrologist for evaluation and subsequent admission if medically necessary.”* [Emphasis in original.]

The applicant adequately demonstrates that Greene County Dialysis Center will provide a range of means by which a person can access the services. Therefore, the application is conforming to this criterion.

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

C

In Section V.3, page 27, the applicant states, “*Greene County Dialysis Center has offered the facility as a clinical learning site for the various nursing programs in the area.*” The information provided in Section V.3 is reasonable and credible for an existing facility and supports a finding of conformity to this criterion.

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

C

The applicant proposes to add five dialysis stations to its existing dialysis facility for a total of 21 certified stations upon completion of the proposed project. The July 2012 SDR shows that there is a deficit of two dialysis stations in Greene County and the applicant proposes to add five stations. The applicant qualifies for up to seven additional dialysis stations based on the facility need methodology in the 2012 SMFP. However, the applicant only proposes to add five stations. DaVita is the only provider of dialysis services in Greene County. The utilization rate currently exceeds 85%.

In Section V.7, page 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. The applicant states:

“Greene County is a rural county. The proposed expansion of the facility is an effort to provide dialysis services to this rural community and is not intended to be a competitive venture. The effect of other facilities in surrounding counties would be difficult to determine since most patients from Greene County already receive treatment at the Greene County Dialysis Center.”

The effect upon competition is unknown. However, patient selection is the determining factor, as the patient will select the provider that gives them the highest quality service and best meets their needs. The Greene County Dialysis Center provides access to all qualified Nephrologists to admit his or her patients.”

See also Sections II, III, V, VI and VII. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that adding five dialysis stations to the existing Greene County Dialysis Center will have a positive impact on cost-effectiveness, quality and access to the proposed services because:

- The applicant adequately demonstrates the need, based on ‘Facility Need,’ to add five dialysis stations for a total of 21 certified dialysis stations following project completion. The applicant also demonstrates that the proposed project will provide additional access to Green County residents and is a cost-effective alternative;
- The applicant adequately demonstrates it will continue to provide quality services. The information regarding staffing provided in Section VII is reasonable and credible and demonstrates adequate staffing for the provision of quality care services in accordance with 42 C.F.R. Section 494 (formerly 405.2100). The information regarding ancillary and support services and coordination of services with the existing health care system in Sections V and VII is reasonable and credible and demonstrates the provision of quality services.
- The applicant adequately demonstrates it will continue to provide adequate access to medically underserved populations. In Section VI.1, page 30, the applicant states:

“Greene County 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. ...”

Therefore, the application is conforming to this criterion.

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

C

According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, the Greene County Dialysis Center operated in compliance with the Medicare Conditions of Participation within the 18 months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

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

C

The Criteria and Standards for End Stage Renal Disease Services 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 APPLICANT

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

.2202(a)(1) Utilization rates;

- C- The utilization rate as of December 31, 2011 as shown in the July 2012 SDR is 85.9%. See Section IV.1, page 23, and Exhibit 7 (copy of the July 2012 SDR, Tables A and B).

.2202(a)(2) Mortality rates;

- C- In Section IV.2, page 23, the applicant reports the 2009, 2010 and 2011 facility mortality rates, which were 18.6%, 12.4%, and 11.3% respectively.

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

- NA- In Section IV.3, page 23, and Section V,2(d), page 26 the applicant states that the Wilson Dialysis Center provides home training for Greene County patients.

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

- C- In Section IV.4, pages 23-24, the applicant stated that Greene County Dialysis Center referred five patients for transplant evaluation in 2011. Greene County Dialysis Center had one patient receive a transplant in 2011.

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

- C- In Section IV.5, page 24, the applicant states that the Greene County Dialysis Center has six patients on the transplant waiting list.

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

- C- See Section IV.6, page 24, the applicant reports a total of 92 hospital admissions in 2011; 78.3% were non-dialysis related and 21.7% were dialysis-related.

.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- In Section IV.7, page 24, the applicant reports that in 2011 there were no patients with an infectious disease and that no patients converted to infectious status in 2011.

(b) An applicant that proposes to develop a new facility, increase the number of dialysis stations in an

existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:

- .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- Greene County 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 transplantation, and,*
- (E) Signatures of the duly authorized persons representing the facilities and the agency providing the services.*
- NA- Greene County 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- Greene County 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 written policies and procedures for back up for 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- Greene County 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, water supply, and other relevant health and safety requirements.*
- C- See Sections VII.2, pages 34-35 and XI.6(e-g), page 54.*
- .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, page 20. Greene County Dialysis Center provides projected patient origin based on historical experience using Greene County's growth rate. The first two years of operation following completion of the project are as follows:*

Greene County Dialysis Center		
County	Operating Year 1	Operating Year 2

	2014	2015
	In-center Patients	In-center Patients
Greene	58	64
Lenoir	4	4
Pitt	4	4
Wilson	2	2
Total	68	74

.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- Greene County Dialysis Center is an 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 for such services.*

-C- In Section II.1(9), page 12, the applicant states, “*Total Renal Care of North Carolina, d/b/a Greene County Dialysis Center will admit and provide dialysis services to patients who have no insurance or other source of payment, if payment for dialysis services is made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.*”

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 station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*

-NA- Greene County 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- In Section III.7, page 20, the applicant projects to serve 68 in-center patients by the end of Year 1, which is 3.2 patients per station (68 / 21 = 3.23) or 81%.

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

-C- In Section II, pages 12-14 and Section III.7, pages 20-21, the applicant provides the assumptions and methodology used to project utilization of the proposed facility.

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- See Section V.1, page 25. Diagnostic evaluation services are provided by Wilson Medical Center, Lenoir Memorial Hospital and Vidant Medical Center-Greenville.
- .2204(2) *Maintenance dialysis;*
 - C- See Section V.1, page 25. Greene County Dialysis Center provides maintenance dialysis.
- .2204(3) *Accessible self-care training;*
 - C- See Section V.1, page 25. Hemodialysis self-care training is provided by Wilson Dialysis Center.
- .2204(4) *Accessible follow-up program for support of patients dialyzing at home;*
 - C- See Section V.1, page 25 and V.2(d), page 26. Accessible follow-up program for support of patients dialyzing at home is provided by Wilson Dialysis Center.
- .2204(5) *X-ray services;*
 - C- See Section V.1, page 25. X-ray services are provided by Wilson Medical Center, Lenoir Memorial Hospital and Vidant Medical Center-Greenville.
- .2204(6) *Laboratory services;*
 - C- See Section V.1, page 25. 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 Wilson Medical Center, Lenoir Memorial Hospital and Vidant Medical Center-Greenville.
- .2204(8) *Emergency care;*
 - C- See Section V.1, page 25. Emergency care is provided by Wilson Medical Center, Lenoir Memorial Hospital and Vidant Medical Center-Greenville.
- .2204(9) *Acute dialysis in an acute care setting;*
 - C- See Section V.1, page 25. Acute dialysis in an acute care setting is provided by Wilson Medical Center, Lenoir Memorial Hospital and Vidant Medical Center-Greenville.
- .2204(10) *Vascular surgery for dialysis treatment patients*
 - C- See Section V.1, page 26. Vascular surgery for dialysis treatment patients is provided by Wilson Medical Center, Lenoir Memorial Hospital and Vidant Medical Center-Greenville.
- .2204(11) *Transplantation services;*
 - C- See Section V.1, page 25. Transplantation services are provided by Duke University Medical Center and Vidant Medical Center- Greenville.
- .2204(12) *Vocational rehabilitation counseling and services; and,*
 - C- See Section V.1, page 25. Vocational rehabilitation counseling and services are provided by the North Carolina Division of Vocational Rehabilitation Services.
- .2204(13) *Transportation*
 - C- See Section V.1, page 26. Transportation is provided by the Department of Social Services and various other providers.

10 NCAC 14C .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- In Section VII.1, page 34, the applicant provides the proposed staffing. In Section VII.2, page 34, the applicant states the proposed facility will comply with all staffing requirements set forth in 42 C.F.R. Section 405.2100. The applicant adequately demonstrates that sufficient staff is proposed for the level of dialysis services to be

provided. See Criterion (7) for discussion which is incorporated hereby as if set forth fully herein.

.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.3, page 35 for the qualifications or certifications held or required for the Greene County Dialysis Center staff. Also see Exhibit 12 for DaVita's training outline, Exhibit 18 for DaVita's Health and Safety Policy and Procedure Manual, and Exhibit 19 for Greene County Dialysis Center's Annual In-Service Calendar.