

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DATE: February 14, 2013

PROJECT ANALYST: Michael J. McKillip

ASSISTANT CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: J-10038-12 / Total Renal Care of North Carolina, LLC d/b/a Wake Forest Dialysis Center / Add five dialysis stations for a total of 15 certified stations upon completion of this project/ Wake County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

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Total Renal Care of North Carolina, LLC d/b/a Wake Forest Dialysis Center [Wake Forest Dialysis Center] proposes to add five dialysis stations for a total of 15 certified dialysis stations upon completion of this project.

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 Wake 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 Wake Forest Dialysis Center in the July 2012 SDR is 3.4 patients per station. This utilization rate was calculated based on 34 in-center dialysis patients and 10 certified dialysis stations as of December 31, 2011 (34 patients / 10 stations = 3.4 patients per station). Application of the facility need methodology indicates five additional stations are needed for this facility, as illustrated in the following table.

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ESRD Facility Need Methodology October Review		
J-10038-12 Wake Forest Dialysis Center		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/2011		85.0%
Certified Stations		10
Pending Stations		0
Total Existing and Pending Stations		10
In-Center Patients as of 12/31/2011 (SDR2)		34
In-Center Patients as of 6/30/2011 (SDR1)		28
Step	Description	
(i)	Difference (SDR2 - SDR1)	6
	Multiply the difference by 2 for the projected net in-center change.	12
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/2011	0.4286
(ii)	Divide the result of Step (i) by 12	0.0357
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/10 to 12/31/11)	0.4286
(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	48.5714
(v)	Divide the result of Step (iv) by 3.2 patients per station	15.1786
	and subtract the number of certified and pending stations as recorded in SDR2 [10] to determine the number of stations needed	5

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

Policy GEN-3: Basic Principles, page 40, of the 2012 SMFP is applicable to this review. Policy GEN-3 states:

“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of

need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

Promote Safety and Quality

The applicant discusses its quality index in Section I, page 7. Also, in Section II.3, page 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....

Dr. Munsoor Lateef 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 company’s 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 51-52. 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 13, the applicant provides a copy of its isolation policies and procedures, in Exhibit 18, a copy of the training manual for injury prevention and safety, and in Exhibit 19, a copy of its in-service calendar. The applicant adequately demonstrates how its proposal will promote safety and quality in the provision of dialysis services in Wake County.

Promote Equitable Access

In Section VI, pages 29-32, the applicant provides information about accessibility to Wake Forest Dialysis Center. On page 29, the applicant states,

“Wake Forest 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.

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

Wake Forest Dialysis Center does not require payment upon admission to its services; therefore, services are available to all patients including low-income persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served persons. Wake Forest Dialysis 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, page 21, the applicant states,

“Wake Forest Dialysis Center promotes cost-effective approaches in the facility in the following ways:

...Wake Forest 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.

Wake Forest Dialysis Center utilizes the reuse process that contains costs and the amount of dialyzer waste generated by the facility. The dialyzers are purchased under a national contract in order to get the best quality dialyzer for the best price.

Wake Forest 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.

Wake Forest 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.

Wake Forest 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 that 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.

In summary, the applicant proposes to add five dialysis stations for a total of 15 dialysis stations. The application is consistent with the facility need determination in the July 2012 SDR and Policy GEN-3. Therefore, the application is conforming to this criterion.

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

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The applicant, Wake Forest Dialysis Center, proposes to add five dialysis stations to its existing facility for a total of 15 certified stations upon completion of this project. In Section IV.1, page 23, the applicant states that the number of in-center patients served at Wake Forest Dialysis Center as of December 31, 2011 is as follows:

Wake Forest Dialysis Center	
County of Residence	Patients Dialyzing In-center
Wake	27
Franklin	7
Total	34

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

Wake Forest Dialysis Center						
County	Operating Year 1 2013-2014		Operating Year 2 2014-2015		County Patients Percent of Total	
	In-center Patients	Home Dialysis Patients	In-center Patients	Home Dialysis Patients	Year 1	Year 2
Wake	38	4	46	5	80.8%	81.0%
Franklin	10	0	12	0	19.2%	19.0%
TOTAL	48	4	58	5	100.0%	100.0%

The applicant adequately identified the population Wake Forest Dialysis Center 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 need for five additional dialysis stations at Wake Forest Dialysis Center. The applicant states,

“Wake Forest Dialysis Center had 34 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 85% based on the 10 certified stations in the facility. The January 2012 Semiannual Dialysis Report indicated that the Wake Forest Dialysis Center had 28 in-center patients as of June 30, 2011, an increase of six patients in the six month period. This calculates to a growth of over 21%. ... We are applying for a five-station expansion of the Wake Forest facility. We have utilized an annual growth rate of 20% to determine the number of patients the facility forecasts to be serving at the end of operating years one and two. This growth rate is less than the actual growth rate based on the actual growth rate between July 1, 2011 and December 31, 2011 (34 in-center patients as of 12/31/11 minus 28 in-center patients as of 06/30/11 = 6 in-center patient increase or 21.4% increase in in-center patient census).

Based on the patients and stations above, the Wake Forest Dialysis Center is projected to have at least 48 in-center patients by the end of operating year 1 for a utilization rate of 80% or 3.2 patients per station and at least 58 in-center patients by the end of operating year 2 for a utilization rate of 96.7% or 3.8 patients per station. This information is based on the calculations below....

July 1, 2012-June 30, 2013 - 34 patients X 1.2 = 40.8

July 1, 2013-June 30, 2014 – 40.8 patients X 1.2 = 48.96

July 1, 2014-June 30, 2015 – 48.96 patients X 1.2 = 58.752

*Operating Year One is projected to begin July 1, 2013 and end on June 30, 2014.
Operating Year Two is projected to begin July 1, 2014 and end on June 30, 2015.*

The number of patients stated in the chart above was rounded down to the nearest whole number.”

Projected utilization at the end of Year One equals 3.2 in-center patients per station per week which is equal to the 3.2 in-center patients per station as required by 10A NCAC 14C .2203(b); and the number of in-center patients projected to be served is based on reasonable, credible and supported assumptions regarding future growth. Between June 30, 2011 and December 31, 2011, the number of in-center patients increased from 28 to 34, which is an increase of 6 patients or 21.4% over a six-month period. The annual rate of change (compound annual growth rate) equals 47.4%. The applicant utilized a rate of growth that is less than half the actual growth rate during 2011. Furthermore, utilization data was obtained from the July 2010, January 2011, July 2011, January 2012 and July 2012 SDRs for Wake Forest Dialysis. Growth rates were calculated at 6 months and 12 months. Utilization was plotted on a graph and a linear regression analysis performed. This analysis substantiated and verified that the applicant's forecast is reasonable and credible.

Access

In Section VI, page 30, the applicant projects that greater than 84% of the patients at Wake Forest Dialysis Center will be covered by Medicare and Medicaid. The applicant demonstrates adequate access for medically underserved groups at Wake Forest Dialysis Center.

In summary, the applicant adequately identifies the population to be served and adequately demonstrates the need for five additional dialysis stations at Wake Forest 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.

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In Section III.9, page 22, the applicant discusses the alternatives considered prior to the submission of this application, which include:

- 1) Maintain the Status Quo – Wake Forest Dialysis Center is at 85% utilization and utilization has been growing rapidly, so this alternative was dismissed.
- 2) The applicant chose to apply for a 5-station expansion of the existing facility to meet the growing demand for dialysis services at Wake Forest Dialysis Center. Between June 30, 2011 and December 31, 2011, utilization increased at a rate of 21.4%. Over a 12-month period, that rate would be 47.4% (CAGR). The applicant projects an annual growth rate of 20% through operating year two, and utilization rates of 80% and 98% in operating years one and two, respectively.

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 the Wake Forest Dialysis Center 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. **Total Renal Care of North Carolina, LLC d/b/a Wake Forest 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 Wake Forest Dialysis Center shall develop and operate no more than five additional dialysis stations for a total of no more than 15 certified stations which shall include any home hemodialysis training or isolation stations.**
 3. **Total Renal Care of North Carolina, LLC d/b/a Wake Forest 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 15 dialysis stations which shall include any isolation stations.**
 4. **Total Renal Care of North Carolina, LLC d/b/a Wake Forest 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.

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In Section VIII.1, page 37, the applicant states that the capital cost is projected to be \$77,000. In VIII.2, the applicant states the capital costs will be financed with the cash reserves of DaVita, Inc., the parent company to Total Renal Care, Inc. and Total Renal Care of North Carolina, LLC. In Section IX.3, page 41, the applicant states there will be no start-up or initial operating expenses associated with the proposed project.

Exhibit 13 includes a letter dated September 14, 2012 from the Chief Accounting Officer of DaVita, Inc., the parent and owner of Total Renal Care of North Carolina, LLC, which states in part:

“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 Inc. will make these funds, along with any other funds that are necessary for the development of the project, available to Total Renal Care of North Carolina, LLC.”

In Exhibit 14, the applicant provides the audited financial statements for DaVita, Inc. for the fiscal year ended December 31, 2011. As of December 31, 2011, DaVita had cash and cash equivalents totaling \$394 million. The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

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

Wake Forest Dialysis Center	
Source of Payment	Charge Per treatment
Commercial Insurance	\$800.00
Medicare/Medicaid	\$240.00
Medicare/Commercial	\$240.00
VA	\$240.00
Medicare	\$192.00
Medicaid	\$192.00

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 45, the applicant reported projected revenues and expenses as follows:

Wake Forest Dialysis Center		
	Operating Year 1	Operating Year 2
Total Net Revenue	\$2,282,848	\$2,710,800

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Total Operating Costs	\$2,074,102	\$2,366,381
Net Profit	\$208,746	\$344,419

The applicant projects that revenue will exceed operating expenses in each of the first two operating years. The assumptions used in preparation of the pro forma financial statements, including the number of projected treatments, are reasonable. See Section X 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 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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Total Renal Care of North Carolina, LLC d/b/a Wake Forest Dialysis Center proposes to add five in-center dialysis stations for a total of 15 dialysis stations upon project completion. Wake Forest Dialysis Center was serving 34 patients weekly at 3.4 patients per station, which is 85% of capacity, as of December 31, 2011. 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 provides reasonable projections for the in-center patient population it proposes to serve on pages 20-21 of the application. The growth projections are based on a projected 20% average annual growth rate in the number of dialysis patients at the Wake Forest facility. At the end of Operating Year Two, the Wake Forest Dialysis Center projects the utilization will be 3.86 in-center patients per station (58 patients / 15 dialysis stations = 3.86). The applicant is not required by either the facility need methodology in the 2012 SMFP or 10A NCAC 14C .2203(b) to demonstrate that other facilities in Wake County are operating at or above a specific utilization rate. The applicant, including related entities, owns only one facility in Wake County. The only other provider of dialysis services in Wake County owns the other 11 facilities. Some of these facilities were approved to add stations pursuant to the facility need methodology even though other facilities owned by the same provider operated at less than 80% of capacity.

The applicant adequately demonstrates the need to develop five additional dialysis stations at 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.

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

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The following table illustrates current and projected staffing for Wake Forest Dialysis Center, as provided by the applicant in Section VII.1, page 33:

Wake Forest Dialysis Center			
Position	Current FTEs	# of FTE Positions to be Added	Total FTE Positions
RN	1.5	0.0	1.5
PCT	4.5	1.5	6.0
Bio-Med Tech	0.5	0.0	0.5
MD	Contract		
Admin	1.0	0.0	1.0
Dietician	0.5	0.0	0.5
Social Worker	0.5	0.0	0.5
Unit Secretary	1.0	0.0	1.0
Other-Reuse	0.5	0.0	0.5
Total	10.0	1.5	11.5

As shown in the above table, the applicant proposes to employ a total of 11.5 full-time equivalent (FTE) positions to staff the Wake Forest Dialysis Center upon completion of the proposed project. In Section VII.2, page 34, the applicant states that Dr. Munsoor Lateef, a board certified nephrologist, will continue to serve as medical director of the facility.

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

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

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Wake Forest Dialysis Center is an existing kidney disease treatment center certified by the Centers for Medicare and Medicaid. According to the records in the Acute and Home Care Licensure and Certification Section, DHSR, the facility meets all conditions of participation,

including any requirements for the provision of ancillary and support services. In Section V.1, page 25, the applicant includes a list of the providers of the necessary ancillary and support services. 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;

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In Section VI.1(b), page 29, the applicant reports that 84.2% of the patients who received treatments at Wake Forest 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 payment sources for the facility:

Wake Forest Dialysis Center	
Source of Payment	Percentage
Medicare/Medicaid	26.3%
Medicare/Commercial	42.1%
Medicare	15.8%
Commercial Insurance	15.8%
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 Wake and Franklin Counties, 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)*
Wake County	10%	3.3%	18.4%
Franklin County	18%	7.4%	19.7%
Statewide	17%	6.7%	19.7%

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

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

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

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

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%

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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

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;

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In Section VI.6 (a), page 32, 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

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In Section VI.1(c), page 30, the applicant provides the projected payor mix for the proposed services at Wake Forest Dialysis Center. The applicant projects no change from the current payor mix for dialysis visits as shown in the table in Criterion (13a) above. The applicant projects that 84.2% of the patients will be Medicare or Medicare/Medicaid beneficiaries. 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.

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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 Wake Forest Dialysis Center. These referrals most commonly come from primary care physicians or specialty physicians in Wake Forest. Patients, families and friends can obtain access by contacting a Nephrologist with privileges at the facility. Should a patient contact the Wake Forest 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 Wake Forest Dialysis Center catchment area requesting transfer to this facility are processed in accordance with the Wake Forest Dialysis Center transfer and transient policies which comprise **Exhibit 9**. The patient, again, is referred to a qualified Nephrologist for final evaluation and subsequent admission if medically necessary.”* (Emphasis in original.)

The applicant adequately demonstrates that Wake Forest Dialysis Center offers 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,

“Wake Forest Dialysis Center has offered the facility as a clinical learning site for the various nursing programs in the area. ... Wake Forest Dialysis Center is open to developing relationships with any program that offers clinical training programs.”

The information provided in Section V.3 is reasonable and credible and supports a finding of conformity to this criterion.

- (15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.

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- (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

Wake Forest Dialysis Center proposes to add five dialysis stations to the existing facility for a total of 15 stations upon completion of the project. The applicant operates one dialysis center in Wake County. Bio-Medical Applications of North Carolina, Inc. (BMA) is the only other provider of dialysis services in Wake County, and operates eleven dialysis centers, as shown in the table below.

Facility	Existing Stations	Approved Not Certified	Total Stations
Cary Kidney Center (BMA)	23	-3	20
FMS of Apex (BMA)	14	2	16
BMA of Raleigh	49	-2	47
FMC of New Hope (BMA)	30	6	36
FMC of Central Raleigh (BMA)	13	2	15
BMA of Fuquay Varina	22	-3	19
Zebulon Kidney Center (BMA)	30	0	30
Wake Dialysis Clinic (BMA)	50	0	50
FMC of Eastern Wake (BMA)	14	0	14
FMC of Millbrook (BMA)	16	1	17
Southwest Wake Dialysis (BMA)	30	1	31

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Wake Forest Dialysis Center*	10	0	10
Total	301	4	305

*Wake Forest Dialysis Center is proposing to add 5 additional stations in this application.

In Section V.7, page 28-29, Wake Forest Dialysis Center discusses the impact of the proposed project on competition 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 include a positive impact on cost-effectiveness, quality and access to dialysis services in Wake County. 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, and that it is a cost-effective alternative to meet that need;
- The applicant adequately demonstrated it will continue to provide quality services; and
- The applicant adequately demonstrated it will continue to provide adequate access to medically underserved populations.

Therefore, the application is conforming to this criterion.

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

C

According to the files of the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, Wake Forest 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 application is conforming to all applicable criteria, which 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- See Section IV.1, page 23, and Exhibit 7 (copy of the July 2012 SDR, Tables A and B), which indicates the facility had an 85% utilization rate as of December 31, 2011.

.2202(a)(2) *Mortality rates;*

-C- In Section IV.2, page 23, the applicant reports 2010 and 2011 facility mortality rates of 17.4% and 17.5%, 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, the applicant states that Wake Forest Dialysis Center had 4 home-trained patients as of June 30, 2012.

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

-C- In Section IV.4, page 24, the applicant stated that Wake Forest Dialysis Center referred 16 patients for transplant evaluation in 2011. Wake Forest Dialysis Center had three patients receive transplants 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 Wake Forest Dialysis Center has 8 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 44 hospital admissions in 2011; 88.6% were non-dialysis related and 11.4% 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 was one patient with an infectious disease. 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- Wake Forest 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- Wake Forest 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- Wake Forest 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- Wake Forest 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 II.3, page 17; VII.2, pages 33-34 and XI.6(g), pages 51-52.*

.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- In Section III.7, page 20, Wake Forest Dialysis Center provided projected patient origin which is based on historical experience, as shown in the table below:

Wake Forest Dialysis Center				
County	Operating Year 1 2013-2014		Operating Year 2 2014-2015	
	In-center Patients	Home Dialysis Patients	In-center Patients	Home Dialysis Patients
Wake	38	4	46	5
Franklin	10	0	12	0
TOTAL	48	4	58	5

.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- Wake Forest 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, page 12, the applicant states, *“Total Renal Care of North Carolina d/b/a Wake Forest 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- Wake Forest 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 Sections II, page 13, and III.7, page 20, the applicant projects to serve 48 in-center patients by the end of Year 1, which is 3.2 patients per station ($48 / 15 = 3.2$).
- .2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section II, pages 12-13 and Section III.7, pages 20-21, the applicant provides the assumptions and methodology used to project utilization of the 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- Provided by Franklin Regional Medical Center. See Section V.1, page 25.
- .2204(2) *Maintenance dialysis;*
- C- Provided by the applicant. See Section V.1, page 25.
- .2204(3) *Accessible self-care training;*
- C- Provided by the applicant. See Section V.1, page 25.
- .2204(4) *Accessible follow-up program for support of patients dialyzing at home;*
- C- Provided by the applicant. See Section V.1, page 25 and V.2(d), page 26.
- .2204(5) *X-ray services;*
- C- Provided by Franklin Regional Medical Center. See Section V.1, page 25.
- .2204(6) *Laboratory services;*
- C- Provided by Dialysis Laboratories. See Section V.1, page 25.
- .2204(7) *Blood bank services;*
- C- Provided by Franklin Regional Medical Center. See Section V.1, page 25.
- .2204(8) *Emergency care;*
- C- Provided by Franklin Regional Medical Center. See Section V.1, page 25.
- .2204(9) *Acute dialysis in an acute care setting;*
- C- Provided by Franklin Regional Medical Center. See Section V.1, page 25.
- .2204(10) *Vascular surgery for dialysis treatment patients*
- C- Provided by Franklin Regional Medical Center. See Section V.1, page 25.
- .2204(11) *Transplantation services;*
- C- Provided by Duke University Hospital. See Section V.1, page 25.
- .2204(12) *Vocational rehabilitation counseling and services; and,*
- C- Provided by NC Division of Vocational Rehabilitation. See Section V.1, page 25.
- .2204(13) *Transportation*
- C- Provided by DSS and various providers. See Section V.1, page 26.

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 33, the applicant provides the proposed staffing.

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In Section VII.2, pages 33-34, the applicant states the proposed facility will comply with all staffing requirements set forth in the Federal code. 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 34, and Exhibits 12, 18 and 19.