

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DATE: February 20, 2014

PROJECT ANALYST: Mike McKillip  
INTERIM CHIEF: Martha Frisone

PROJECT I.D. NUMBER: J-10204-13 / Total Renal Care of North Carolina, LLC d/b/a Wake Forest Dialysis Center / Add five dialysis stations for a total of 18 certified stations upon completion of this project and Project I.D. # K-10126-13 / 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 18 certified dialysis stations upon completion of this project and Project I.D. K-10126-13.

The 2013 State Medical Facilities Plan (2013 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2013 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 2013 SDR is 4.8 patients per station. This utilization rate was calculated based on 48 in-center dialysis patients and 10 certified dialysis stations as of December 31, 2012 (48 patients / 10 stations = 4.8 patients per station). Effective March 17, 2013 (Project I.D. #J-10038-12), Wake Forest Dialysis Center was

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approved to add five dialysis stations for a total of fifteen stations [10 + 5 = 15]. In Project I.D. # K-10126-13, Wake Forest Dialysis applied to relocate two dialysis stations from Wake Forest Dialysis Center to a new facility in Franklin County. Therefore, Wake Forest Dialysis Center would operate 18 certified stations upon completion of this project and Project I.D. # K-10126-13 [15 – 2 + 5 = 18]. However, on September 25, 2013, Project I.D. # K-10126-13 was denied. Thus, upon completion of this project, Wake Forest Dialysis Center would be certified for 20 stations [15 + 5 = 20]. Application of the facility need methodology indicates five additional stations are needed for this facility, as illustrated in the following table.

**OCTOBER 1 REVIEW-JULY SDR**

Required SDR Utilization		80%
Center Utilization Rate as of 12/31/12		80.0%
Certified Stations		15
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>15</b>
In-Center Patients as of 12/31/12 (SDR2)		48
In-Center Patients as of 6/30/12 (SDR1)		41
Step	Description	
(i)	Difference (SDR2 - SDR1)	7
	Multiply the difference by 2 for the projected net in-center Change	14
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/12	0.3415
(ii)	Divide the result of Step (i) by 12	0.0285
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/11 until 12/31/12)	0.3415
(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	64.3902
(v)	Divide the result of Step (iv) by 3.2 patients per station	20.1220
	and subtract the number of certified and pending stations as recorded in SDR2 [15] 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 only five new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policy GEN-3: Basic Principles, page 42, of the 2013 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.13, page 7. Also, in Section II.3, pages 17-18, the applicant states,

*“DaVita Healthcare Partners, 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 56-57. In Exhibit 4 the applicant provides published articles about its clinical outcomes and quality incentive program (QIP). In Exhibit 14, the applicant provides a copy of its isolation policies and procedures, in Exhibit 16, a copy of the training policies and procedures, including health and

safety training. 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 31-34, the applicant provides information about accessibility to Wake Forest Dialysis Center. On page 31, 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, pages 22-23, 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 that the proposal will maximize healthcare value. Consequently, the applicant demonstrates that the projected volumes for the proposed service incorporate the basic principles in meeting the needs of the patients to be served. The application is consistent with the facility need determination in the July 2013 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.

## C

The applicant, Wake Forest Dialysis Center, proposes to add five dialysis stations to its existing facility for a total of 18 certified stations upon completion of this project and Project I.D. # K-10126-13. However, on September 25, 2013, Project I.D. # K-10126-13 was denied. Thus, upon completion of this project, Wake Forest Dialysis Center would be certified for 20 stations. In Section IV.1, page 24, the applicant states that 34 in-center patients served at Wake Forest Dialysis Center were residents of Wake County, 12 in-center patients were residents of Franklin County, one was a resident of Durham County, and one was a resident of Johnston County, as of December 31, 2012.

### **Population to be Served**

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In Section III.7, page 21, 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 CY2015		Operating Year 2 CY2016		County Patients Percent of Total	
	In-center Patients	Home Dialysis Patients	In-center Patients	Home Dialysis Patients	Year 1	Year 2
Wake	50	12	56	14	76.6%	76.1%
Franklin	17	0	20	0	21.0%	21.7%
Durham	1	0	1	0	1.2%	1.1%
Johnston	1	0	1	0	1.2%	1.1%
TOTAL	69	12	78	14	100.0%	100.0%

The applicant adequately identified the population Wake Forest Dialysis Center proposes to serve.

Demonstration of Need

In Section II.1, 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,

*“The Wake Forest Dialysis Center had 48 in-center patients as of December 31, 2012 based on information contained in Table A of the July 2013 Semiannual Dialysis Report. This is a station utilization rate of 80% based on the 15 certified stations in the facility. The January 2013 Semiannual Dialysis Report indicated that the Wake Forest Dialysis Center had 41 in-center patients as of June 30, 2012, an increase of 7 in-patients in a six month period. This calculates to a growth of 17%. ... We are applying for a five-station expansion of the Wake Forest facility. We have utilized an annual growth rate of 13% 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 one half of the actual growth rate based on the actual growth rate between July 1, 2012 and December 31, 2012 (48 in-center patients as of 12/31/12 minus 41 in-center patients as of 06/30/12 = 7 in-center patient increase or 17% increase in in-center patient census for a six-month period)....*

*Based on the patients and stations above, the Wake Forest Dialysis Center is projected to have at least 69 in-center patients by the end of operating year 1 for a utilization rate of 86% or 3.4 patients per station and at least 78 in-center patients by the end of operating year 2 for a utilization rate of 97% or 3.9 patients per station. [Note: These*

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utilization rates are based on the assumption that the facility will have 20 certified stations.] *This information is based on the calculations below....*

*January 1, 2013-December 31, 2013 – 48 in-center patients X 1.13 = 54.24*  
*January 1, 2014-December 31, 2014 – 54.24 in-center patients X 1.13 = 61.2912*  
*January 1, 2015-December 31, 2015 – 61.2912 in-center patients X 1.13 = 69.259056*  
*January 1, 2016-December 31, 2016 – 69.259056 in-center patients X 1.13 = 78.26273328*

*Operating Year One is projected to begin January 1, 2015 and end on December 31, 2015.*

*Operating Year Two is projected to begin January 1, 2016 and end on December 31, 2016.*

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

It should be noted that the applicant’s projected utilization for the first two operating years, as described in Section III.7 of the application and shown above, is based on the assumption that Wake Forest Dialysis Center will have 20 certified stations, rather than 18 stations. Wake Forest Dialysis Center’s application (Project I.D. # K-10126-13) to relocate two of its dialysis stations to a new facility in Youngsville (Franklin County) was denied by the CON Section on September 25, 2013, and has been appealed by the applicant. In the public hearing comments from November 20, 2013, the applicant states,

*“If a settlement is reached on the denial of Youngsville Dialysis and the facility is developed, then two of the Wake Forest Dialysis Center stations and eleven of the in-center patients would transfer their care to the Youngsville facility when it becomes certified. That would leave Wake Forest Dialysis Center with 18 dialysis stations and 58 in-center patients for a utilization rate of 80% at the end of operating year one and 67 in-center patients for a utilization rate of 93% at the end of operating year two.”*

Projected utilization at the end of Year One equals 3.4 in-center patients per station per week which is greater than 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, 2012 and December 31, 2012, the number of in-center patients increased from 41 to 48, which is an increase of 7 patients or 17.1% over a six-month period. The annual rate of change (compound annual growth rate) equals 37.1%. The applicant utilized a rate of growth that is less than half the actual growth rate during 2012. Furthermore, utilization data was obtained from the July 2010, January 2011, July 2011, January 2012, July 2012, January 2013, and July 2013 SDRs for Wake Forest Dialysis Center. 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.1, page 32, the applicant projects that greater than 68.2% 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, demonstrates the need the population has for five additional stations at Wake Forest Dialysis Center, and demonstrates all residents of the area, and, in particular, underserved groups are likely to have access to the services proposed. Therefore, the application is conforming to this criterion.

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

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 80% 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, 2012 and December 31, 2012, utilization increased at a rate of 17%. Over a 12-month period, that rate would be 37.1% (CAGR). The applicant projects an annual growth rate of 13% through operating year two, and utilization rates of 86% and 97% 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 20 certified stations upon completion of this project, which shall include any isolation or home hemodialysis 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 20 dialysis stations which shall include any isolation or home hemodialysis 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 40, the applicant states that the capital cost is projected to be \$94,423. In VIII.2, the applicant states the capital costs will be financed with the cash reserves of DaVita Healthcare Partners, Inc., the parent company to Total Renal Care, Inc. and Total Renal Care of North Carolina, LLC. In Section IX.3, page 44, the applicant states there will be no start-up or initial operating expenses associated with the proposed project.

Exhibit 17 includes a letter dated September 6, 2013 from the Chief Accounting Officer of DaVita Healthcare Partners, Inc., which states in part:

*“The project calls for a capital expenditure of \$94,423. This letter will confirm that DaVita Healthcare Partners, Inc. has committed cash reserves in the total sum of \$94,423 for the project capital expenditure. DaVita Healthcare Partners, 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 18, the applicant provides the audited financial statements for DaVita Healthcare Partners, Inc. for the fiscal year ended December 31, 2012. As of December 31, 2012, DaVita had cash and cash equivalents totaling \$534 million. The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

In Section X.1, page 46, the applicant provides projected allowable charges per treatment for each payment source as follows:

<b>Wake Forest Dialysis Center</b>	
Source of Payment	Charge Per treatment
Commercial Insurance	\$1,442.00
Medicare/Medicaid	\$253.55
Medicare/Commercial	\$253.55
VA	\$193.00
Medicare	\$202.84
Medicaid	\$143.00

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

<b>Wake Forest Dialysis Center</b>		
	<b>Operating Year 1</b>	<b>Operating Year 2</b>
Total Net Revenue	\$6,321,055	\$7,193,314
Total Operating Costs	\$3,931,088	\$4,410,892
Net Profit	\$2,389,967	\$2,782,422

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 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 (charges) 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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Wake Forest Dialysis Center, the only dialysis facility operated by the applicant in Wake County, proposes to add five in-center dialysis stations for a total of 18 dialysis stations upon project completion. Wake Forest Dialysis was serving 48 patients weekly on 15 stations, which is 3.2 patients per station or 80% of capacity, as of December 31, 2012. 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 21-22 of the application. The growth projections are based on a projected 13% average annual growth rate in the number of dialysis patients at the Wake Forest Dialysis Center facility. At the end of Operating Year Two, Wake Forest Dialysis Center projects the utilization will be 3.9 in-center patients per station (78 patients / 20 dialysis stations = 3.9), which is 97% 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 application is conforming to this criterion.

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

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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 35:

<b>Wake Forest Dialysis Center</b>			
<b>Position</b>	<b>Current FTEs</b>	<b># of FTE Positions to be Added</b>	<b>Total FTE Positions</b>
RN	2.0	1.0	3.0
HTRN	1.0	0.0	1.0
PCT	6.0	2.0	8.0
Bio-Med Tech	0.5	0.0	0.5
MD	Contract		
Admin	1.0	0.0	1.0
Dietician	0.5	0.2	0.7
Social Worker	0.5	0.2	0.7
Unit Secretary	1.0	0.0	1.0
Other-Reuse	0.5	0.0	0.5
<b>Total</b>	<b>13.0</b>	<b>3.4</b>	<b>16.4</b>

As shown in the above table, the applicant proposes to employ a total of 16.4 full-time equivalent (FTE) positions to staff the Wake Forest Dialysis Center upon completion of the proposed project. In Section VII.2, page 36, the applicant states that Dr. Munsoor Lateef, a board certified nephrologist, will continue to serve as medical director of the facility.

The applicant has documented 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.

C

In Section V.1, page 26, the applicant includes a list of providers of the necessary ancillary and support services. Exhibit 12 contains a letter from the medical director of the facility expressing his support for the proposed project. 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 31, the applicant reports that 68.2% 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:

<b>Wake Forest Dialysis Center</b>
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Source of Payment	Percentage
Medicare/Medicaid	12.1%
Medicare/Commercial	31.9%
Medicare	21.2%
Medicaid	3.0%
Commercial Insurance	27.3%
VA	4.5%
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 County and statewide.

County	Total # of Medicaid Eligibles as % of Total Population June 2010*	Total # of Medicaid Eligibles Age 21 and older as % of Total Population June 2010*	% Uninsured CY 2008-2009* (Estimate by Cecil G. Sheps Center)
Wake	10%	3.3%	18.4%
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, in 2011 only 5.8% of all newly-diagnosed ESRD patients (incident ESRD patients) in North Carolina's Network 6 were under the age of 35.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race 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.

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.”*

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:

<b>ESRD Spending by Payor</b>		
<b>Payor</b>	<b>Spending in Billions</b>	<b>% of Total Spending</b>
Medicare Paid	\$29.6	62.32%
Medicare Patient Obligation	\$4.7	9.89%
Medicare HMO	\$3.4	7.16%
Non-Medicare	\$9.8	20.63%

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

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

<b>Number and Percent of Dialysis Patients by Age, Race and Gender</b>		
	<b># of ESRD Patients</b>	<b>% of Dialysis Population</b>

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<b>Ages</b>		
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%
<b>Gender</b>		
Female	4,237	45.35%
Male	5,105	54.65%
<b>Race</b>		
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;

C

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.1(f), page 32, the applicant states:

*“Wake Forest Dialysis Center has no obligation under any applicable federal regulation to provide uncompensated care, community service or access by minorities and handicapped persons except those obligations which are placed upon all medical facilities under Section 504 of the Rehabilitation Act of 1973 and its subsequent amendment in 1993.”*

In Section VI.6 (a), page 34, the applicant states there have been no patient 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 32, the applicant provides the projected payer mix for the proposed services at Wake Forest Dialysis Center.

Wake Forest Dialysis Center	
Source of Payment	Percentage
Medicare/Medicaid	12.1%
Medicare/Commercial	31.9%
Medicare	21.2%
Medicaid	3.0%
Commercial Insurance	27.3%
VA	4.5%
Total	100.0%

The applicant projects no change from the current payer mix for in-center dialysis services, which indicates that 68.2% of patients will have some or all of their services paid by Medicare and Medicaid. 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 33, 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 13**. 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 28 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.  
(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 18 stations upon completion of this project and Project I.D. # K-10126-13. However, on September 25, 2013, Project I.D. # K-10126-13 was denied. Thus, upon completion of this project, Wake Forest Dialysis Center would be certified for 20 stations [15 + 5 = 20]. The applicant operates one dialysis center in Wake County. Bio-Medical Applications of North

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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.

**Wake County Dialysis Facilities**

<b>Dialysis Facility</b>	<b>Certified Stations 12/31/12</b>	<b>% Utilization</b>	<b>Patients Per Station</b>
BMA of Fuquay-Varina	22	79.55%	3.2
BMA of Raleigh Dialysis	47	83.51%	3.3
BMA Cary	23	85.87%	3.4
FMC Apex (BMA)	14	82.14%	3.3
FMC Central Raleigh (BMA)	15	58.33%	2.3
FMC Eastern Wake (BMA)	14	71.43%	2.9
FMC Millbrook (BMA)	17	75.00%	3.0
FMC New Hope (BMA)	29	75.86%	3.0
Southwest Wake (BMA)	31	84.68%	3.4
Wake Dialysis (BMA)	50	87.00%	3.5
Wake Forest Dialysis Center*	10	120.00%	4.8
Zebulon Kidney Center (BMA)	30	75.00%	3.0

Source: July 2013 SDR, Table A.

\*Effective March 17, 2013 (Project I.D. #J-10038-12), Wake Forest Dialysis Center was approved to add five dialysis stations for a total of fifteen stations [10 + 5 = 15]. In Project I.D. # K-10126-13, Wake Forest Dialysis applied to relocate two dialysis stations from Wake Forest Dialysis Center to a new facility in Franklin County. Therefore, Wake

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Forest Dialysis Center would operate 18 certified stations upon completion of this project and Project I.D. # J-10126-13 [ $15 - 2 + 5 = 18$ ]. However, on September 25, 2013, Project I.D. # K-10126-13 was denied. Thus, upon completion of this project, Wake Forest Dialysis Center would be certified for 20 stations [ $15 + 5 = 20$ ].

As shown in the table above, seven of the twelve Wake County dialysis facilities are operating above 80% utilization (3.2 patients per station), and eleven of the twelve facilities are operating at or above 70% utilization (2.8 patients per station).

In Section V.7, pages 29-30, the applicant discusses how any enhanced competition in the service area would have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states,

*“The proposed expansion of the facility is an effort to provide dialysis services to this urban community and is not intended to be a competitive venture. Fresenius Medical Care operates eleven dialysis facilities in Wake County and has a Certificate of Need application to develop a twelfth facility in the county. Until the Wake Forest Dialysis Center was awarded to Total Renal Care of North Carolina several years ago, Fresenius Medical Care had a monopoly on the provision of in-center dialysis services in Wake County. ... 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 Wake Forest Dialysis Center provides access to all qualified Nephrologists to admit his or her patients. ... As of December 31, 2012, Fresenius Medical Care had 272 certified stations and was treating 935 in-center patients. Fresenius had 94.8% of the certified dialysis stations and 95.9% of the in-center patients. The addition of five dialysis stations at Wake Forest Dialysis Center will have no negative impact on the competitor in Wake County.”*

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 any enhanced competition in the service area will have a positive impact on cost-effectiveness, quality and access to the proposed services. 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 at the Wake Forest Dialysis Center facility and that it is a cost-effective alternative;
- ◆ The applicant adequately demonstrates that it will continue to provide quality services; and
- ◆ The applicant demonstrates that it will continue to provide adequate access to medically underserved populations.

The application is conforming to this criterion.

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

C

According to 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 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- See Section III.1, page 19, which indicates the facility had an 80% utilization rate as of December 31, 2012.

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

-C- In Section IV.2, page 24, the applicant reports 2010, 2011 and 2012 facility mortality rates of 17.4%, 17.5% and 11.4%, respectively.

- .2202(a)(3) *The number of patients that are home trained and the number of patients on home dialysis;*
- C- In Section IV.3, page 24, the applicant states that Wake Forest Dialysis Center had six patients home-trained in peritoneal dialysis as of December 31, 2012.
- .2202(a)(4) *The number of transplants performed or referred;*
- C- In Section IV.4, page 25, the applicant states Wake Forest Dialysis Center referred seven patients for transplant evaluation in 2012, and no patients received a transplant in 2012.
- .2202(a)(5) *The number of patients currently on the transplant waiting list;*
- C- In Section IV.5, page 25, the applicant states that Wake Forest Dialysis Center has four 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 25, the applicant reports a total of 44 hospital admissions in 2012; 40 were non-dialysis related and 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 25, the applicant reports that in 2012 there was one patient with an infectious disease, and no patients converted to infectious status in 2012.
- (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 Section VII.2, pages 35-36 and XI.6(g), pages 56-57.  
.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 21, Wake Forest Dialysis Center provided projected patient origin based on historical experience for the first two years of operation following completion of the project. See Criterion (3) for discussion regarding projected patient origin which is incorporated hereby as if set forth fully herein.  
.2202(b)(8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*
- NA- 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.1, page 13 and III.7, page 21, the applicant projects to serve 69 in-center patients by the end of Operating Year 1, which is 3.4 patients per station ( $69 / 20 = 3.4$ ). See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if set forth fully herein.
- .2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section II.1, pages 12-15 and Section III.7, pages 21-22, the applicant provides the assumptions and methodology used to project utilization of the proposed facility. See Criterion (3) for discussion which is incorporated hereby as if set forth fully herein.

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

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

- .2204(1) *Diagnostic and evaluation services;*  
-C- Provided by Duke Raleigh Hospital. See Section V.1, page 26.
- .2204(2) *Maintenance dialysis;*  
-C- Provided by the applicant. See Section V.1, page 26.
- .2204(3) *Accessible self-care training;*  
-C- Provided by the applicant. See Section V.1, page 26.
- .2204(4) *Accessible follow-up program for support of patients dialyzing at home;*  
-C- Provided by the applicant. See Section V.1, page 26 and V.2(d), page 27.
- .2204(5) *X-ray services;*  
-C- Provided by Duke Raleigh Hospital. See Section V.1, page 26.
- .2204(6) *Laboratory services;*  
-C- Provided by Dialysis Laboratories. See Section V.1, page 26.
- .2204(7) *Blood bank services;*  
-C- Provided by Duke Raleigh Hospital. See Section V.1, page 26.
- .2204(8) *Emergency care;*  
-C- Provided by Duke Raleigh Hospital. See Section V.1, page 26.
- .2204(9) *Acute dialysis in an acute care setting;*  
-C- Provided by Duke Raleigh Hospital. See Section V.1, page 26.

- .2204(10) *Vascular surgery for dialysis treatment patients*
  - C- Provided by Duke Raleigh Hospital. See Section V.1, page 26.
- .2204(11) *Transplantation services;*
  - C- Provided by Duke University Hospital. See Section V.1, page 26.
- .2204(12) *Vocational rehabilitation counseling and services; and,*
  - C- Provided by NC Division of Vocational Rehabilitation. See Section V.1, page 26.
- .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 35, the applicant provides the proposed staffing.  
In Section VII.2, pages 36, 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 regarding projected staffing 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 36, and Exhibit 16.