

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 18, 2015

Findings Date: December 18, 2015

Project Analyst: Mike McKillip

Assistant Chief: Martha Frisone

Project ID #: J-11090-15

Facility: Wake Forest Dialysis Center

FID #: 041181

County: Wake

Applicant: Total Renal Care of North Carolina, LLC

Project: Add two dialysis stations for a total of 22 stations

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Total Renal Care of North Carolina, LLC d/b/a Wake Forest Dialysis Center [Wake Forest Dialysis Center] proposes to add two dialysis stations for a total of 22 certified dialysis stations upon completion of the project.

Need Determination

The 2015 State Medical Facilities Plan (2015 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2015 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of only one dialysis station in Wake County; therefore, based on the county need methodology, there is no need for additional stations 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 2015 SDR is 3.65 patients per station. This utilization rate was calculated based on 73 in-center dialysis patients and 20 certified dialysis stations as of December 31, 2014 (73 patients / 20 stations = 3.65 patients per station). Application of the facility need methodology indicates eleven additional stations are needed for this facility, as illustrated in the following table.

OCTOBER 1 REVIEW - JULY 2015 SDR

Required SDR Utilization		80%
Center Utilization Rate as of 12/31/14		91.3%
Certified Stations		20
Pending Stations		0
Total Existing and Pending Stations		20
In-Center Patients as of 12/31/14 (July 2015 SDR) (SDR2)		73
In-Center Patients as of 6/30/14 (January 2015 SDR) (SDR1)		62
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	11
	Multiply the difference by 2 for the projected net in-center change	22
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/14	0.3548
(ii)	Divide the result of step (i) by 12	0.0296
(iii)	Multiply the result of step (ii) by 12 (the number of months from 12/31/13 until 12/31/14)	0.3548
(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	98.9032
(v)	Divide the result of step (iv) by 3.2 patients per station	30.9073
	and subtract the number of certified and pending stations to determine the number of stations needed	11

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is eleven 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 two new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2015 SMFP which is applicable to this review: Policy GEN-3: Basic Principles. 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.”

The applicant addresses Policy GEN-3 as follows:

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section B.4.(a), pages 9-10, Section O, page 54, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section B.4.(b), page 10, Section L, pages 47-51, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value – The applicant describes how it believes the proposed project would maximize healthcare value in Section B.4.(c) and (d), page 11. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need as identified by the applicant. The application is consistent with Policy GEN-3.

Conclusion

In summary, the applicant adequately demonstrates that the application is consistent with the facility need determination in the July 2015 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 two dialysis stations for a total of 22 certified dialysis stations upon completion of the project.

Population to be Served

On page 361, the 2015 SMFP defines the service area for dialysis stations as *“the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.”* Thus, the service area is Wake County. Facilities may serve residents of counties not included in their service area.

In Section C.8, pages 18-19, the applicant provides the historical patient origin for Wake Forest Dialysis Center for in-center and home patients as of December 31, 2014, which is summarized in the following table:

	IN-CENTER		HOME*	
	PATIENTS	PERCENT	PATIENTS	PERCENT
Wake	53	72.6%	14	77.8%
Franklin	9	12.3%	3	16.7%
Vance	2	2.7%	0	0.0%
Halifax	1	1.4%	0	0.0%
Johnston	1	1.4%	0	0.0%
Mecklenburg	1	1.4%	0	0.0%
Durham	0	0.0%	1	5.5%
Other States	5	6.8%	0	0.0%
Total	73	100.0%	18	100.0%

*The “Home” category includes peritoneal dialysis patients.

In Section C.1, page 13, the applicant provides the projected patient origin for Wake Forest Dialysis Center for in-center and home patients for the first two years of operation following completion of the project as follows:

	OPERATING YEAR 1 CY2017		OPERATING YEAR 2 CY2018		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	IN-CENTER	HOME*	IN-CENTER	HOME*	YEAR 1	YEAR 2
Wake	61	17	64	18	76.5%	77.5%
Franklin	9	3	9	3	11.8%	11.3%
Vance	2	0	2	0	1.9%	1.9%
Halifax	2	0	2	0	1.9%	1.9%
Johnston	1	0	1	0	1.0%	1.0%
Mecklenburg	1	0	1	0	1.0%	0.9%
Durham	0	1	0	1	1.0%	0.9%
Other States	5	0	5	0	4.9%	4.7%
Total	81	21	84	22	100.0%	100.0%

*The “Home” category includes home hemodialysis and peritoneal dialysis patients.

The applicant provides the assumptions and methodology used to project patient origin on page 13. The applicant adequately identifies the population to be served.

Analysis of Need

In Section B.2, pages 6-7, the applicant states the application is filed pursuant to the facility need methodology in the 2015 SMFP utilizing data from the July 2015 SDR, and it proposes to add two dialysis stations to Wake Forest Dialysis Center for a total of 22 stations at that facility. The applicant used the following assumptions:

1. The applicant projects the first two full operating years of the project will be CY2017 and CY2018.
2. On December 31, 2014, Wake Forest Dialysis Center was providing dialysis treatment for 73 in-center patients, including 53 patients who reside in Wake County, and twenty patients who reside in other counties and states.
3. Wake Forest Dialysis Center assumes the Wake County ESRD in-center patient population utilizing the facility will increase at the rate of 5.0 percent per year. On page 13, the applicant states,

“The following [utilization projections] are the in-center patient projections using the 5% Average Annual Change Rate for the Past Five Years as indicated in Table B of the July 2015 SDR for the 53 in-center patients living in Wake County. No growth calculations were performed for the twenty patients living in other counties and states.”

Projected Utilization

The applicant’s methodology is illustrated in the following table.

	In-Center
The applicant begins with the facility census of Wake County in-center residents as of December 31, 2014.	53
The census of Wake County in-center patients is increased by 5.0% to project the census forward to December 31, 2015.	$53 \times 1.05 = 55.65$
The census of Wake County in-center patients is increased by 5.0% to project the census forward to December 31, 2016.	$55.65 \times 1.05 = 58.425$
The census of Wake County in-center patients is increased by 5.0% to project the census forward to December 31, 2017.	$58.4325 \times 1.05 = 61.354$
Add twenty in-center patients from other counties and states. This is the projected ending census for Operating Year 1.	$61.354 + 20 = 81.354$
The census of Wake County in-center patients is increased by 5.0% for one year to December 31, 2018.	$61.354 \times 1.05 = 64.4218$
Add twenty in-center patients from other counties and states. This is the projected ending census for Operating Year 2.	$64.4218 + 20 = 84.4218$

The applicant projects to serve 81 in-center patients or 3.7 patients per station ($81/22 = 3.7$) by the end of Operating Year 1 and 84 in-center patients or 3.80 patients per station ($84/22 = 3.8$) by the end of Operating Year 2 for the proposed 22-station facility. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b). The July 2015 SDR indicates that Wake Forest Dialysis Center operated at a utilization rate of 91.3 percent (3.7 patients per station). In this application, the applicant assumes a projected annual rate of growth of 5.0% for the Wake County in-center patient census at Wake Forest Dialysis Center, which is consistent with the Wake County Five Year Average Annual Change Rate (2010-2014). Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

Access

In Section L.1(a), pages 56-57, the applicant states that Wake Forest Dialysis Center makes its services available to all persons without qualification, including low-income, racial and ethnic minorities, women, handicapped, elderly, and other underserved persons. The applicant projects 89% of its patients will be Medicare or Medicaid recipients. The applicant adequately demonstrates the extent to which all residents of the service area, including underserved groups, are likely to have access to its services.

Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for two additional stations at Wake Forest Dialysis Center, and demonstrates the extent to which all residents of the area, including 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.

CA

In Section E.1, page 23, the applicant states the only other alternative to the proposed project that was considered prior to submitting this application was to maintain the status quo. However, the applicant states that maintaining the status quo is not an effective alternative due to the lack of capacity at the facility to meet the growing demand for services at the Wake Forest Dialysis Center.

After considering the alternatives, the applicant states the alternative represented in the application is the most effective alternative to meet the identified need.

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 proposal is the least costly or most effective alternative to meet the identified 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 two additional dialysis stations for a total of no more than 22 certified stations upon completion of the 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 acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

In Section F.1, page 25, the applicant states that it projects \$63,858 in capital costs to develop this project. In Sections F.10-F.12, pages 27-28, the applicant states there will be no start-up expenses or initial operating expenses incurred for this project.

Availability of Funds

In Section F.2, page 26, the applicant states it will finance the capital costs with accumulated reserves. Exhibit F-5 contains a letter dated September 10, 2015 from the Vice President of Tax for DaVita HealthCare Partners, Inc. (DHP), the parent company for the applicant, which states the applicant has adequate funds for the proposed project. Exhibit F-7 contains the Securities and Exchange Commission Form 10-K for DHP which indicates that it had \$965 million in cash and cash equivalents as of December 31, 2014. The applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project.

Financial Feasibility

The applicant provided pro forma financial statements for the first two years of the project. In the pro forma financial statement (Form B), the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

	CY2017	CY2018
Total Net Revenue	\$5,759,475	\$5,998,027
Total Operating Expenses	\$4,081,030	\$4,231,753
Net Income	\$1,678,445	\$1,766,274

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See the financial section of the application for the assumptions used regarding costs and charges. The discussion of utilization projections found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Conclusion

In summary, the applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project. Furthermore, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

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

C

The applicant, Wake Forest Dialysis Center, proposes to add two dialysis stations for a total of 22 certified dialysis stations upon completion of the project.

On page 361, the 2015 SMFP defines the service area for dialysis stations as *“the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.”* Thus, the service area is Wake County. Facilities may serve residents of counties not included in their service area.

The applicant operates just 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.

Wake County Dialysis Facilities

Dialysis Facility	Certified Stations 12/31/14	% Utilization	Patients Per Station
BMA of Fuquay-Varina	19	88.16%	3.5
BMA of Raleigh Dialysis	50	81.00%	3.2
BMA Cary	28	67.86%	2.7
FMC Apex (BMA)	17	72.06%	2.9
FMC Central Raleigh (BMA)	15	95.00%	3.8
FMC Eastern Wake (BMA)	14	100.00%	4.0
FMC Millbrook (BMA)	17	88.24%	3.5
FMC New Hope (BMA)	36	76.39%	3.1
Southwest Wake (BMA)	31	85.48%	3.4
BMA Wake Dialysis	50	96.50%	3.9
Wake Forest Dialysis (DaVita)	20	91.25%	3.7
Zebulon Kidney Center (BMA)	30	82.50%	3.3

Source: July 2015 SDR, Table A.

As shown in the table above, nine of the twelve Wake County dialysis facilities are operating above 80% utilization (3.2 patients per station), and ten of the twelve facilities are operating at or above 75% utilization (3.0 patients per station).

Wake Forest Dialysis Center proposes to add two in-center dialysis stations for a total of 22 dialysis stations upon project completion. Wake Forest Dialysis Center was serving 73 patients weekly on 20 stations, which is 3.65 patients per station or 91.25% of capacity, as of December 31, 2014. 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 13-15 of the application. The growth projections are based on a projected 5.0% average annual growth rate in the number of Wake County 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 3.8 in-center patients per station (84 patients / 22 dialysis stations = 3.8), which is 95% of capacity. The applicant adequately demonstrates the need to develop two 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 dialysis stations or facilities. Therefore, 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.

C

In Section H.1, page 33, the applicant provides the current and proposed staffing for the facility, which includes 45.52 full-time equivalent (FTE) employees. The applicant proposes to add one FTE technician as a result of this project. In Section H.3, pages 34-35, the applicant describes its experience and process for recruiting and retaining staff. Exhibit I-3 contains a copy of a letter from Munsoor Lateef, M.D., expressing his interest in serving as the Medical Director for the facility. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed 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 I.1, page 37, the applicant includes a list of providers of the necessary ancillary and support services. Exhibit I-3 contains a copy of a letter from the medical director for the facility expressing his support for the proposed project, and describing the facility's

established relationships with other healthcare providers. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

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

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations 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 R, *Form C - Revenue Assumptions*, the applicant reports that 89% of the in-center 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 shows the historical (CY2014) payment source for the facility for in-center patients:

Payment Source	In-Center
Medicare	27.4%
Medicaid	1.4%
Commercial Insurance	9.6%
Medicare/Commercial	43.8%
Medicare/Medicaid	16.4%
VA	1.4%
Total	100.00%

The Division of Medical Assistance (DMA) maintains a website which provides the number of persons eligible for Medicaid in North Carolina, and estimates the percentage of uninsured people for each county. The following table illustrates those percentages for Wake County and statewide.

	2010 Total # of Medicaid Eligibles as % of Total Population *	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	2008-2009 % Uninsured (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.

Although the majority of Medicaid eligibles are children under the age of 21, they represent a very small percentage of those who utilize the services offered by dialysis facilities. In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older. (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59*).¹

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina, as well as data sorted by age, race or gender. But it does not include information on the number of elderly, handicapped, minorities or women utilizing health services.

¹<http://www.esrdnetwork6.org/utlils/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

However, the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report* provides prevalence data on North Carolina dialysis patients by age, race and gender on page 59, summarized as follows:

Number and Percent of Dialysis Patients by Age, Race, and Gender 2014		
	# of ESRD Patients	% of Dialysis Population
Age		
0-19	52	0.3%
20-34	770	4.8%
35-44	1,547	9.7%
45-54	2,853	17.8%
55-64	4,175	26.1%
65+	6,601	41.3%
Gender		
Female	7,064	44.2%
Male	8,934	55.8%
Race		
African-American	9,855	61.6%
White	5,778	36.1%
Other, inc. not specified	365	2.3%

Source: Southeastern Kidney Council Network 6 Inc. 2014 Annual Report.²

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

²<http://www.esrdnetwork6.org/utills/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section L.3, page 50, 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 L.6, page 51, the applicant states there have been no civil rights access complaints filed within the last five years. Therefore, the application is conforming to this criterion.

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

C

In Section L.1, page 48, the applicant projects that 89% of the in-center patients who will receive treatments at Wake Forest Dialysis Center in the second operating year (CY2018) will have some or all of their services paid for by Medicare or Medicaid. The table below shows the projected Year 2 payment source for the facility for in-center patients:

Payment Source	In-Center
Medicare	27.4%
Medicaid	1.4%
Commercial Insurance	9.6%
Medicare/Commercial	43.8%
Medicare/Medicaid	16.4%
VA	1.4%
Total	100.00%

In Section L.1, page 48, the applicant provides the assumptions used to project payer mix. The applicant's projected payment sources are consistent with the facility's historical (CY2014) payment sources as reported by the applicant in Section R. The applicant demonstrated that medically underserved groups will have adequate access to the services offered at Wake Forest Dialysis Center. 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 L.4, page 50, the applicant describes the range of means by which a person will have access to the dialysis services at Wake Forest Dialysis Center, including referrals from nephrologists. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to dialysis 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 M.1, page 52, the applicant states that Wake Forest Dialysis Center has established relationships with local community training programs. Exhibit M-1 contains a copy of correspondence to an area health professional training program expressing an interest on the part of the applicant to offer the facility as a clinical training site. The information provided is reasonable and adequately supports a determination that the application is conforming 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 two dialysis stations for a total of 22 stations upon completion of the project.

On page 361, the 2015 SMFP defines the service area for dialysis stations as *“the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.”* Thus, the service area is Wake County. Facilities may serve residents of counties not included in their service area.

The applicant operates one dialysis center in Wake County. 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

Dialysis Facility	Certified Stations 12/31/14	% Utilization	Patients Per Station
BMA of Fuquay-Varina	19	88.16%	3.5
BMA of Raleigh Dialysis	50	81.00%	3.2
BMA Cary	28	67.86%	2.7
FMC Apex (BMA)	17	72.06%	2.9
FMC Central Raleigh (BMA)	15	95.00%	3.8
FMC Eastern Wake (BMA)	14	100.00%	4.0
FMC Millbrook (BMA)	17	88.24%	3.5
FMC New Hope (BMA)	36	76.39%	3.1
Southwest Wake (BMA)	31	85.48%	3.4
BMA Wake Dialysis	50	96.50%	3.9
Wake Forest Dialysis (DaVita)	20	91.25%	3.7
Zebulon Kidney Center (BMA)	30	82.50%	3.3

Source: July 2015 SDR, Table A.

As shown in the table above, nine of the twelve Wake County dialysis facilities are operating above 80% utilization (3.2 patients per station), and ten of the twelve facilities are operating at or above 75% utilization (3.0 patients per station).

In Section N.1, page 53, the applicant discusses how any enhanced competition would have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states,

“The expansion of the Wake Forest Dialysis Center will have no effect on competition in Wake County. The addition of two stations at this facility serves to address the needs of a population already served (or projected to be served, based on historical growth rates) by Total Renal Care of North Carolina, LLC and not any other providers in the service area.

The expansion of Wake Forest Dialysis Center will enhance accessibility to dialysis for our patients, and by reducing the economic and physical burdens on our patients, this project will enhance the quality and effectiveness of our services because it will make it easier for patients, family members and others involved in the dialysis process to receive services.”

See also Sections B, C, E, F, G, H and L where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information in the application is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on the 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 for the project and that it is a cost-effective alternative. The discussions regarding the analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates it will provide quality services. The discussion regarding quality found in Criteria (1) and (20) is incorporated herein by reference.
- The applicant demonstrates that it will provide adequate access to medically underserved populations. The discussion regarding access found in Criteria (1) and (13) is incorporated herein by reference.

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

In Exhibit O-3, the applicant identifies three kidney disease treatment centers located in North Carolina, owned and operated by the applicant, that were cited in the past 18 months for deficiencies in compliance with 42 CFR Part 494, the Centers for Medicare and Medicaid (CMS) Conditions for Coverage of ESRD facilities. In Section O.3, page 54, the applicant states all three facilities are back in full compliance with CMS Guidelines as of the date of submission of this application. Exhibit O-3 contains copies of letters documenting that the facilities were determined to be back in compliance by the Centers for Medicare and Medicaid Services and the Division of Health Service Regulation. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. 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 application is conforming with all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. 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- In Section B.2, page 31, the applicant reports the facility had 73 in-center patients and a 91% utilization rate as of December 31, 2014.

.2202(a)(2) Mortality rates;

-C- In Section C.9, page 19, the applicant reports 2012, 2013, and 2014 facility mortality rates of 12.2%, 11.2% and 18.2%, respectively.

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

-NA- In Section C.8, pages 18-19, the applicant reports that Wake Forest Dialysis Center had 18 peritoneal dialysis patients as of December 31, 2014.

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

-C- In Section C.10, page 19, the applicant states Wake Forest Dialysis Center referred 6 patients for transplant evaluation in 2014.

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

-C- In Section C.10, page 19, 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- In Section C.11, page 19, the applicant reports a total of 130 hospital admissions, of which 106 were non-dialysis related and 24 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 C.10, page 19, the applicant reports that in 2015 there are currently two patients with an infectious disease, and no patients converted to infectious status in the last calendar year.

(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 K-1 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- In Section K.1, page 43, the applicant states 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.

.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 C.1, page 13, Wake Forest Dialysis Center provides projected patient origin, based on historical experience, for the first two years of operation following completion of the project. The discussion regarding patient origin assumptions found in Criterion (3) is incorporated herein by reference.

.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 L.3, page 49, the applicant states, “*Wake Forest Dialysis Center admits and provides 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 Section C.1, page 13, the applicant projects to serve 81 in-center patients by the end of Operating Year 1, which is 3.7 patients per station ($81 / 22 = 3.7$). The discussion regarding utilization assumptions found in Criterion (3) is incorporated herein by reference.

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

-C- In Section C.1, pages 13-15 the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding utilization assumptions found in Criterion (3) is incorporated herein by reference.

10 NCAC 14C .2204 SCOPE OF SERVICES

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

.2204(1) *Diagnostic and evaluation services;*

-C- These services are provided by WakeMed. See Section I.1, page 38.

.2204(2) *Maintenance dialysis;*

-C- Provided at Wake Forest Dialysis Center. See Section I.1, page 38.

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

-C- Provided by Wake Forest Dialysis Center. See Section I.1, page 38.

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

-C- Provided by Wake Forest Dialysis Center. See Section I.1, page 38.

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

-C- These services are provided by WakeMed. See Section I.1, page 38.

.2204(6) *Laboratory services;*

-C- Provided by DaVita Laboratory Services, Inc. See Section I.1, page 38.

.2204(7) *Blood bank services;*

-C- Provided by WakeMed. See Section I.1, page 38.

.2204(8) *Emergency care;*

-C- Provided by WakeMed. See Section I.1, page 38.

.2204(9) *Acute dialysis in an acute care setting;*

-C- Provided by WakeMed. See Section I.1, page 38.

.2204(10) *Vascular surgery for dialysis treatment patients*

-C- Provided by referral to Wake Heart and Vascular. See Section I.1, page 38.

.2204(11) *Transplantation services;*

-C- Provided by Duke University Medical Center. See Section I.1, page 38.

.2204(12) *Vocational rehabilitation counseling and services; and,*

-C- Provided by referral to North Carolina Division of Vocational Rehabilitation. See Section I.1, page 38.

.2204(13) *Transportation*

-C- Provided by Wake Human Services. See Section I.1, page 38.

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 H.1, page 33, the applicant provides the proposed staffing. In Section H.2, page 34, the applicant states the proposed facility will comply with all staffing requirements set forth in 42 C.F.R. Section 494 (formerly 405.2100). The applicant adequately demonstrates that sufficient staff is proposed for the level of dialysis services to be provided. The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

.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 H.4, page 35, and Exhibits H-2 and H-4.