

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 9, 2016

Findings Date: December 9, 2016

Project Analyst: Mike McKillip

Team Leader: Fatimah Wilson

Project ID #: J-11254-16

Facility: Wake Forest Dialysis Center

FID #: 041181

County: Wake

Applicant: Total Renal Care, Inc.

Project: Add two dialysis stations for a total of 15 stations upon completion of this project, Project I.D. # J-11090-15 (Add two dialysis stations), Project I.D. # J-11131-16 (Relocate 10 stations from Wake Forest Dialysis Clinic to a new facility in Raleigh) and Project I.D. # J-11152-16 (Add one dialysis station)

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §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, Inc. d/b/a Wake Forest Dialysis Center [**Wake Forest Dialysis Center**] proposes to add two dialysis stations for a total of 15 stations upon completion of this project, Project I.D. # J-11090-15 (Add two dialysis stations), Project I.D. # J-11131-16 (Relocate 10 stations from Wake Forest Dialysis Clinic to a new facility in Raleigh) and Project I.D. # J-11152-16 (Add one dialysis station).

**Need Determination**

The 2016 State Medical Facilities Plan (2016 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2016 Semiannual Dialysis Report (SDR), the county need methodology shows there is no county need determination for 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 2016 SDR is 3.75 patients per station per week. This utilization rate was calculated based on 75 in-center dialysis patients and 20 certified dialysis stations as of December 31, 2015 (75 patients / 20 stations = 3.75 patients per station per week). Application of the facility need methodology indicates two additional stations are needed for this facility, as illustrated in the following table.

<b>OCTOBER 1 REVIEW-JULY SDR</b>		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/15		93.8%
Certified Stations		20
Pending Stations		3
<b>Total Existing and Pending Stations</b>		<b>23</b>
In-Center Patients as of 12/31/15 (SDR2)		75
In-Center Patients as of 6/30/15 (SDR1)		73
<b>Step</b>	<b>Description</b>	<b>Result</b>
(i)	Difference (SDR2 - SDR1)	2
	Multiply the difference by 2 for the projected net in-center change	4
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/15	0.0548
(ii)	Divide the result of step (i) by 12	0.0046
(iii)	Multiply the result of step (ii) by 12 (the number of months from 12/31/14 until 12/31/15)	0.0548
(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	79.1096
(v)	Divide the result of step (iv) by 3.2 patients per station	24.7217
	and subtract the number of certified and pending stations to determine the number of stations needed	<b>2</b>

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is two 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 2016 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 51, 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 44-48, 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, and Section N, page 50. 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 2016 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 15 stations upon completion of this project, Project I.D. # J-11090-15 (Add two dialysis stations), Project I.D. # J-11131-16 (Relocate 10 stations from Wake Forest Dialysis Clinic to a new facility in Raleigh) and Project I.D. # J-11152-16 (Add one dialysis station).

**Patient Origin**

On page 369, the 2016 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, page 19, the applicant provides the historical patient origin for Wake Forest Dialysis Center patients as of December 31, 2015, which is summarized in the following table:

**Wake Forest Dialysis Center Historical Patient Origin**

County	In-Center	Home Hemodialysis	Peritoneal Dialysis
Wake	53	0	18
Durham	1	0	1
Franklin	12	0	5
Johnston	1	0	0
Pitt	1	0	0
Vance	2	0	0
Other States	5	0	0
<b>TOTAL</b>	<b>75</b>	<b>0</b>	<b>24</b>

Source: Table on page 19 of the application.

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

County	Operating Year 1 CY2018			Operating Year 2 CY2019			Percent of Total	
	IC	HH	PD	IC	HH	PD	OY1	OY2
Wake	40	0	13	42	0	14	70.7%	71.8%
Durham	0	0	0	0	0	0	0.0%	0.0%
Franklin	12	0	5	12	0	5	22.7%	21.8%
Johnston	0	0	0	0	0	0	0.0%	0.0%
Pitt	0	0	0	0	0	0	0.0%	0.0%
Vance	2	0	0	2	0	0	2.7%	2.6%
Other States	3	0	0	1	0	0	4.0%	3.8%
<b>Total</b>	<b>57</b>	<b>0</b>	<b>18</b>	<b>59</b>	<b>0</b>	<b>19</b>	<b>100.0%</b>	<b>100.0%</b>

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 2016 SMFP utilizing data from the July 2016 SDR, and it proposes to add two dialysis stations to Wake Forest Dialysis Center for a total of 15 stations at that facility. The applicant used the following assumptions on pages 13-15 of the application:

1. The applicant projects the first two full operating years of the project will be January 1, 2018 – December 31, 2018 (CY2018) and January 1, 2019 – December 31, 2019 (CY2019).
2. On December 31, 2015, Wake Forest Dialysis Center was providing dialysis treatment for 75 in-center patients, including 53 patients who reside in Wake County, one patient who resides in Durham County, 12 patients who reside in Franklin County, one patient who resides in Johnston County, one patient who resides in Pitt County, two patients who reside in Vance County, and five patients who reside in other states.
3. Wake Forest Dialysis Center assumes the in-center patient population utilizing the facility who reside in Wake County will increase at the rate of 5.6 percent per year, which is the Five Year (2011-2015) Average Annual Change Rate for Wake County in Table B of the July 2016 SDR. On page 18, the applicant states,

*“The following [utilization projections] are the in-center patient projections using the 5.6% Average Annual Change Rate for the Past Five Years as indicated in Table B of the July 2016 SDR for the 53 in-center patients living in Wake County. ... No growth calculations were performed for the patients living outside of Wake County.*

*After the period of growth ending 2017, there will be 81 in-center patients, 59 of them from Wake County (see line (c) [on page 14]). When we deduct the 21 Wake County*

*patients and the 5 patients from outside of Wake County who are projected to transfer to Oak City Dialysis upon certification, Wake Forest Dialysis Center will have 38 Wake County patients at the beginning of 2018 (see line (d) [on page 14]).”*

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, 2015.	53
The census of Wake County in-center patients is increased by 5.6% to project the census forward one year to December 31, 2016.	$53 \times 1.056 = 55.968$
The census of Wake County in-center patients is increased by 5.6% to project the census forward one year to December 31, 2017.	$55.968 \times 1.056 = 59.10221$
The applicant subtracts 21 Wake County patients from the projected in-center census who are projected to transfer to Oak City Dialysis.	$59 - 21 = 38$
The census of Wake County in-center patients is increased by 5.6% to project the census forward one year to December 31, 2018.	$38 \times 1.056 = 40.128$
The applicant adds 17 patients who reside outside Wake County. This is the projected ending census for Operating Year 1.	$40.128 + 17 = 57.128$
The census of Wake County in-center patients is increased by 5.6% to project the census forward one year to December 31, 2019.	$40.128 \times 1.056 = 42.37517$
The applicant adds 17 patients who reside outside Wake County. This is the projected ending census for Operating Year 2.	$42.37517 + 17 = 59.37517$

The applicant projects to serve 57 in-center patients or 3.8 patients per station per week ( $57/15 = 3.8$ ) by the end of Operating Year 1 and 59 in-center patients or 3.9 patients per station per week ( $59/15 = 3.9$ ) by the end of Operating Year 2 for the proposed 15-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 2016 SDR indicates that Wake Forest Dialysis Center operated at a utilization rate of 93.75 percent (3.75 patients per station) as of December 31, 2015. Based on data reported in the SDR, during the period from June 30, 2015 to December 31, 2015, the in-center census at Wake Forest Dialysis

Center increased from 73 to 75 patients, which is an annual rate of growth of 5.5 percent. In this application, the applicant assumes a projected annual rate of growth of 5.6 percent for the in-center patient census at Wake Forest Dialysis Center, which is equal to the Wake County Five Year Average Annual Change Rate (2011-2015), and nearly identical to the applicant's recent historical experience. Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

### *Peritoneal Dialysis*

On page 15, the applicant provides the following table showing its projections of peritoneal dialysis patients through the first two operating years of the project.

<b>PD Patient Projections</b>	<b>Start Date</b>	<b># of Patients Start of Year</b>	<b># of Patients End of Year</b>	<b>Average # of Patients in Year</b>
Interim Period 1	1/1/2016	24	25	24.5
Interim Period 2	1/1/2017	25	26	25.5
Operating Year 1	1/1/2018	26 – 9 = 17	18	17.5
Operating Year 2	1/1/2019	18	19	18.5

Source: Table on page 15 of the application.

On page 15, the applicant describes its assumptions as follows:

*“Wake Forest Dialysis Center had 24 peritoneal dialysis patients as of December 31, 2015 based on information included in Table A of the July 2016 SDR. ... The period of growth begins January 1, 2018 and is calculated forward to December 31, 2019. It is reasonable to assume that the Wake Forest home-training program will grow at a rate of at least one patient per year during the period of growth. ... Nine (9) Wake County PD patients are projected to transfer to Oak City Dialysis upon its certification. After the period of growth ending in 2017, there will be 26 PD patients at Wake Forest Dialysis Center. When we deduct the 9 patients who are projected to transfer to Oak City Dialysis upon certification, Wake Forest Dialysis Center will have 17 Wake County patients at the beginning of 2018.”*

### **Access**

In Section L.1(a), pages 44-45, 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. In Section L.7, page 48, the applicant reports that 85% 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 CY2015. In Section L.1, page 45, the applicant projects 86% 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 that alternative, 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, Inc. d/b/a Wake Forest Dialysis Center shall materially comply with all representations made in the certificate of need application.**
- 2. Total Renal Care, Inc. 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 15 certified stations upon completion of the project, Project I.D. # J-11090-15, Project I.D. # J-11131-16, and Project I.D. # J-11152-16, which shall include any isolation or home hemodialysis stations.**

- 3. Total Renal Care, Inc. 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 24, the applicant states that it will not incur any capital costs to develop this project. In Sections F.10-F.12, pages 26-27, the applicant states there will be no start-up expenses or initial operating expenses incurred for this 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.

	<b>CY2018</b>	<b>CY2019</b>
Total Treatments	10,960	11,486
Total Charges	\$3,985,389	\$4,169,578
Total Net Revenue	\$3,867,752	\$4,047,194
Total Operating Expenses	\$3,083,825	\$3,205,175
Net Income	\$783,927	\$842,020

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 regarding projected utilization 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 the financial feasibility of the proposal is based upon reasonable and adequately supported assumptions regarding projected utilization, 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.

C

The applicant, Wake Forest Dialysis Center, proposes to add two dialysis stations for a total of 15 stations upon completion of this project, Project I.D. # J-11090-15 (Add two dialysis stations), Project I.D. # J-11131-16 (Relocate 10 stations from Wake Forest Dialysis Clinic to a new facility in Raleigh) and Project I.D. # J-11152-16 (Add one dialysis station).

On page 369, the 2016 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.

Wake Forest Dialysis Center (DaVita) is one of two providers of dialysis services in Wake County, and currently operates just one dialysis center. DaVita has been approved to develop one additional facility in Wake County, Oak City Dialysis, but the facility was not yet operational on December 31, 2015. BMA operates eleven dialysis centers in Wake County. Also, BMA has been approved to develop two additional facilities in Wake County, FMC Northern Wake and FMC Morrisville, but the facilities were not yet operational on December 31, 2015. The existing and approved Wake County dialysis facilities are shown below:

**Wake County Dialysis Facilities**

Dialysis Facility	Certified Stations 12/31/15	CON Issued Not Certified	% Utilization	Patients Per Station
BMA of Fuquay-Varina	22	0	95.45%	3.8
BMA of Raleigh Dialysis	50	0	92.50%	3.7
Cary Kidney Center (BMA)	28	-4	75.89%	3.0
FMC Apex (BMA)	20	0	58.75%	2.4
FMC Central Raleigh (BMA)	19	0	75.00%	3.0
FMC Eastern Wake (BMA)	14	3	110.71%	4.4
FMC Millbrook (BMA)	17	0	82.35%	3.3
FMC Morrisville (BMA)	0	10	NA	NA
FMC New Hope (BMA)	36	0	72.22%	2.9
FMC Northern Wake (BMA)	0	3	NA	NA
Oak City Dialysis (DaVita)	0	10	NA	NA
Southwest Wake (BMA)	31	-6	95.16%	3.8
Wake Dialysis Clinic (BMA)	50	0	102.50%	4.1
Wake Forest Dialysis (DaVita)	20	12	93.75%	3.8
Zebulon Kidney Center (BMA)	30	-2	81.67%	3.3

Source: July 2016 SDR, Table A.

As shown in the table above, eight of the twelve operational Wake County dialysis facilities were operating above 80% utilization (3.2 patients per station), and ten of the twelve operational facilities were operating at or above 75% utilization (3.0 patients per station) as of December 31, 2015.

Wake Forest Dialysis Center proposes to add two in-center dialysis stations for a total of 15 dialysis stations upon project completion. Wake Forest Dialysis Center was serving 75 patients weekly on 20 stations, which is 3.75 patients per station or 93.75% of capacity, as of December 31, 2015. 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 5.6% average annual growth rate in the number of in-center dialysis patients at the Wake Forest Dialysis facility. At the end of Operating Year Two, Wake Forest Dialysis Center projects utilization will be 3.9 in-center patients per station (59 patients / 15 dialysis stations = 3.9), which is 97.5% 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 31, the applicant provides the current staffing for the facility, which includes 16.5 full-time equivalent (FTE) employees. The applicant states that one FTE administrator is projected to be added to the proposed staffing for the facility following completion of the project, for a total of 17.5 FTEs. In Section H.3, pages 32-33, the applicant describes its experience and process for recruiting and retaining staff, and states that it does not anticipate difficulties in hiring the required staff for this project. Exhibit I contains a copy of a letter from Munsoor Lateef, M.D., expressing his interest in continuing to serve 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 35, and referenced exhibits, the applicant includes a list of providers of the necessary ancillary and support services. Exhibit I contains a letter from the medical director of the facility expressing his support for the proposed project. In Section I.4, page 37, the applicant states that Wake Forest Dialysis Center is an existing facility with established relationships with the existing Wake County health care system. 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 L.7, page 48, the applicant reports that 85% 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 CY2015. The table below shows the historical (CY2015) payment source for the facility for in-center patients:

Payment Source	In-Center Patients by Percent of Total
Medicare	27.7%
Commercial Insurance	13.8%
Medicare/Commercial	43.2%
Medicare/Medicaid	13.8%
VA	1.5%
<b>Total</b>	<b>100.00%</b>

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant's service area.

Percent of Population						
County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
Wake	10%	51%	39%	12%	5%	14%
Statewide	15%	51%	36%	17%	10%	15%

Source: <http://www.census.gov/quickfacts/table>, 2014 Estimate as of December 22, 2015.

\*Excludes "White alone" who are "not Hispanic or Latino"

\*\*"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

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

<b>Number and Percent of Dialysis Patients by Age, Race, and Gender 2014</b>		
	<b># of ESRD Patients</b>	<b>% of Dialysis Population</b>
<b>Age</b>		
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%
<b>Gender</b>		
Female	7,064	44.2%
Male	8,934	55.8%
<b>Race</b>		
African-American	9,855	61.6%
White	5,778	36.1%
Other, inc. not specified	365	2.3%

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

In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older and over 63% were non-Caucasian. (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59*).

The applicant adequately demonstrates that it currently 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;

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 47, 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 47, 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(b), page 45, the applicant projects that 86% of the in-center patients who will receive treatments at Wake Forest Dialysis Center in the second operating year (CY2019) 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:

<b>Payment Source</b>	<b>In-Center Patients by Percent of Total</b>
Medicare	27.7%
Commercial Insurance	13.8%
Medicare/Commercial	43.2%
Medicare/Medicaid	13.8%
VA	1.5%
<b>Total</b>	<b>100.0%</b>

In Section L.1, pages 44-45, the applicant provides the assumptions used to project payer mix. The applicant's projected payment sources are consistent with the facility's historical (CY2015) payment sources as reported by the applicant in Section L.7, page 48, and with the applicant's pro forma financial statements (Form B) included in Section R of the application. 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 47, 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 and other physicians. 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 49, the applicant states that Wake Forest Dialysis Center has established relationships with local community training programs, and the applicant will continue to offer the same opportunities to local health professional training programs. Exhibit M 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 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

The applicant, Wake Forest Dialysis Center, proposes to add two dialysis stations for a total of 15 stations upon completion of this project, Project I.D. # J-11090-15 (Add two dialysis stations), Project I.D. # J-11131-16 (Relocate 10 stations from Wake Forest Dialysis Clinic to a new facility in Raleigh) and Project I.D. # J-11152-16 (Add one dialysis station).

On page 369, the 2016 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.*

Wake Forest Dialysis Center (DaVita) is one of two providers of dialysis services in Wake County, and currently operates just one dialysis center. DaVita has been approved to develop one additional facility in Wake County, Oak City Dialysis, but the facility was not yet operational on December 31, 2015. BMA operates eleven dialysis centers in Wake County. Also, BMA has been approved to develop two additional facilities in Wake County, FMC Northern Wake and FMC Morrisville, but the facilities were not yet operational on December 31, 2015. The existing and approved Wake County dialysis facilities are shown below:

**Wake County Dialysis Facilities**

<b>Dialysis Facility</b>	<b>Certified Stations 12/31/15</b>	<b>CON Issued Not Certified</b>	<b>% Utilization</b>	<b>Patients Per Station</b>
BMA of Fuquay-Varina	22	0	95.45%	3.8
BMA of Raleigh Dialysis	50	0	92.50%	3.7
Cary Kidney Center (BMA)	28	-4	75.89%	3.0
FMC Apex (BMA)	20	0	58.75%	2.4
FMC Central Raleigh (BMA)	19	0	75.00%	3.0
FMC Eastern Wake (BMA)	14	3	110.71%	4.4
FMC Millbrook (BMA)	17	0	82.35%	3.3
FMC Morrisville (BMA)	0	10	NA	NA
FMC New Hope (BMA)	36	0	72.22%	2.9
FMC Northern Wake (BMA)	0	3	NA	NA
Oak City Dialysis (DaVita)	0	10	NA	NA
Southwest Wake (BMA)	31	-6	95.16%	3.8
Wake Dialysis Clinic (BMA)	50	0	102.50%	4.1
Wake Forest Dialysis (DaVita)	20	12	93.75%	3.8
Zebulon Kidney Center (BMA)	30	-2	81.67%	3.3

Source: July 2016 SDR, Table A.

As shown in the table above, eight of the twelve operational Wake County dialysis facilities were operating above 80% utilization (3.2 patients per station), and ten of the twelve operational facilities were operating at or above 75% utilization (3.0 patients per station) as of December 31, 2015.

In Section N.1, page 50, 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.*

*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 discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- The applicant demonstrates that it will provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (1), (3) and (13) are 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 four 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 51, the applicant states all four 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:

**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 57 in-center patients by the end of Operating Year 1, which is 3.8 patients per station ( $57 / 15 = 3.8$ ). The discussion regarding projected utilization 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

projected utilization found in Criterion (3) is incorporated herein by reference.