

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: January 7, 2019

Findings Date: January 7, 2019

Project Analyst: Celia C. Inman

Team Leader: Fatimah Wilson

Project ID #: J-11597-18

Facility: Wake Forest Dialysis Center

FID #: 041181

County: Wake

Applicant: Total Renal Care of North Carolina, LLC

Project: Add 3 stations for a total of 18 stations upon completion of this project, Project I.D. #J-11131-16 (relocate 10 stations to Oak City Dialysis), Project I.D. #J-11152-16 (add 1 station), and Project I.D. #J-11254-16 (add 2 stations)

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 of North Carolina, LLC (TRC) d/b/a Wake Forest Dialysis Center (WFDC), the applicant, proposes to develop three additional dialysis stations for a total of 18 stations upon completion of this project, Project ID #J-11131-16 (relocate ten stations to Oak City Dialysis), Project ID #J-11152-16 (add one station), and Project ID #J-11254-16 (add two stations). TRC is a DaVita related provider of dialysis services.

Need Determination

The 2018 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2018 Semiannual Dialysis Report (SDR), the county need methodology shows there is an 11 station surplus and therefore 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 WFDC in the July 2018 SDR is 3.77 patients per station per week. This utilization rate was calculated based on 83 in-center dialysis patients and 22 certified dialysis stations as of December 31, 2017 (83 patients / 22 stations = 3.77 patients per station per week). Application of the facility need methodology indicates up to three additional stations are needed for this facility, as illustrated in the following table.

OCTOBER 1 REVIEW-JULY 2018 SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/17		94.32%
Certified Stations		22
Pending Stations		3
Total Existing and Pending Stations		25
In-Center Patients as of 12/31/17 (July 2018 SDR) (SDR2)		83
In-Center Patients as of 6/30/17 (Jan 2018 SDR) (SDR1)		80
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	3
	Multiply the difference by 2 for the projected net in-center change	6
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/17	0.075
(ii)	Divide the result of Step (i) by 12	0.006
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/16 until 12/31/17)	0.075
(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	89.225
(v)	Divide the result of Step (iv) by 3.2 patients per station	27.883
	and subtract the number of certified and pending stations to determine the number of stations needed (rounded)	3

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

Policies

There is one policy in the 2018 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.”

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, 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 45-49; 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), page 11, and Section N, page 51. 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.

In summary, the applicant adequately demonstrates that the application is consistent with the facility need determination in the July 2018 SDR and Policy GEN-3. Therefore, the application is conforming to this criterion.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

- (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 proposes to develop three additional dialysis stations for a total of 18 stations upon completion of this project, Project ID #J-11131-16 (relocate ten stations to Oak City Dialysis), Project ID #J-11152-16 (add one station), and Project ID #J-11254-16 (add two stations).

The following table illustrates the current and projected number of dialysis stations at WFDC, based on existing certified stations, as of December 31, 2017, per the July 2018 SDR and pending relocations and additions.

Stations	Description	Project ID #
22	Total existing certified stations as of the July 2018 SDR	
+3	Stations to be added at WFDC as part of this project	J-11597-18
+1	Stations approved to be added but not yet certified	J-11152-16
+2	Stations approved to be added but not yet certified	J-11254-16
-10	Stations approved to be deleted but not yet certified – Oak City Dialysis	J-11131-16
18	Total stations upon completion of proposed project	

As shown in the table above, upon project completion, WFDC will be certified for 18 dialysis stations, assuming completion of this project, Project ID #J-11131-16 (relocate ten stations to Oak City Dialysis), Project ID #J-11152-16 (add one station), and Project ID #J-11254-16 (add two stations).

Patient Origin

On page 365, the 2018 SMFP defines the service area for dialysis stations as “*the dialysis station 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.*” Wake Forest Dialysis Center is located in Wake County; thus, the service area for this facility consists of Wake County. Facilities may also serve residents of counties not included in their service area.

In Section C.8, page 19, the applicant provides the historical patient origin for WFDC patients as of December 31, 2017, which is summarized in the following table:

**Wake Forest Dialysis Center Historical Patient Origin
 As of December 31, 2017**

County	In-Center	Home Hemodialysis	Peritoneal Dialysis
Wake	57	0	11
Durham	1	0	0
Franklin	14	0	3
Johnston	3	0	0
New Hanover	1	0	0
Vance	1	0	0
Georgia	1	0	0
Tennessee	1	0	0
Other States	4	0	0
TOTAL	83	0	14

Source: Table on page 19 of the application.

Tables B and C, pages 50 and 57, respectively, of the July 2018 SDR, show the same information as provided above regarding in-center (IC), home hemodialysis (HH), and peritoneal (PD) patients, as of December 31, 2017.

In Section C.1, page 13, the applicant provides the projected IC and PD patient origin for WFDC for the first two years of operation following completion, as shown in the following table:

Wake Forest Dialysis Center Projected Patient Origin

County	Operating Year 1 (OY1)			Operating Year 2 (OY2)			Percent of Total IC and PD Patients	
	IC	HH	PD	IC	HH	PD	OY1	OY2
Wake	41	0	11	43	0	11	64.2%	65.1%
Durham	1	0	0	1	0	0	1.2%	1.2%
Franklin	14	0	3	14	0	3	21.0%	20.5%
Johnston	3	0	0	3	0	0	3.7%	3.6%
New Hanover	1	0	0	1	0	0	1.2%	1.2%
Vance	1	0	0	1	0	0	1.2%	1.2%
Georgia	1	0	0	1	0	0	1.2%	1.2%
Tennessee	1	0	0	1	0	0	1.2%	1.2%
Other States	4	0	0	4	0	0	4.9%	4.8%
TOTAL	67	0	14	69	0	14	100.0%	100.0%

In Section C, pages 13-15, the applicant provides the assumptions and methodology used to project its patient origin. However, the table on page 13, and summarized above, does not agree with the assumptions and methodology as provided on pages 13-15. In response to clarifying information requested by the Agency, the applicant states that the patient origin table on page 13 inadvertently includes incorrect patient origin numbers. The table above

fails to deduct the five patients from outside of Wake County who are expected to transfer to Oak City Dialysis. The table above also holds the PD patient numbers constant, while the methodology and assumptions grow the PD patients by one patient per year. The corrected patient origin, as clarified by the applicant and in agreement with the applicant’s utilization methodology and assumptions is as follows.

**Wake Forest Dialysis Center Projected Patient Origin
 As Clarified by the Applicant**

County	Operating Year 1 (OY1)			Operating Year 2 (OY2)			Percent of Total IC and PD Patients	
	IC	HH	PD	IC	HH	PD	OY1	OY2
Wake	41	0	14	43	0	15	69.6%	70.7%
Durham	0	0	0	0	0	0	0.0%	0.0%
Franklin	14	0	3	14	0	3	21.5%	20.7%
Johnston	0	0	0	0	0	0	0.0%	0.0%
New Hanover	0	0	0	0	0	0	0.0%	0.0%
Vance	1	0	0	1	0	0	1.3%	1.2%
Georgia	1	0	0	1	0	0	1.3%	1.2%
Tennessee	1	0	0	1	0	0	1.3%	1.2%
Other States	4	0	0	4	0	0	5.1%	4.9%
TOTAL	62	0	17	64	0	18	100.0%	100.0%

Totals may not sum due to rounding.

The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section B.2, page 7, the applicant provides the ESRD Facility Need Methodology table, showing the application is filed pursuant to the facility need methodology in the 2018 SMFP, utilizing data from the July 2018 SDR. The applicant proposes to add three dialysis stations to WFDC for a total of 18 stations upon completion of this project, Project ID #J-11131-16 (relocate ten stations to Oak City Dialysis), Project ID #J-11152-16 (add one station), and Project ID #J-11254-16 (add two stations).

The applicant uses the following assumptions, as discussed in Section C.7, pages 17-19:

1. The July 2018 SDR shows that WFDC operated at a utilization rate of 94.32% (3.77 patients per station) as of December 31, 2017, and had 83 in-center patients. The applicant states that 57 of the 83 patients were residents of Wake County.
2. The applicant projects the first full operating year (OY1) of the project will be January 1, 2020 – December 31, 2020 (CY2020) and the second full operating year (OY2) will be January 1, 2021 – December 31, 2021 (CY2021).
3. Project ID #O-11131-16 approved the development of Oak City Dialysis in Wake County via relocation of 10 stations from WFDC. The applicant states that 26 in-center patients are projected to transfer their care from WFDC to Oak City Dialysis

upon its projected certification date of January 2019 (21 patients from Wake County and five patients from outside of Wake County).

- The applicant assumes the Wake County in-center patient population utilizing the facility will increase at the Wake County Average Annual Change Rate (AACR) of 4.3% per year. On pages 17-18, the applicant states,

“The following are the in-center patient projections using the 4.3% Average Annual Change Rate for the Past Five Years as indicated in Table D of the July 2018 SDR for the 57 in-center patients living in Wake County. The period of growth begins July 1, 2018 and is calculated forward to December 31, 2021. No growth calculations were performed for the patient living outside of Wake County.”

The applicant further states that after the period of growth ending in 2018, there will be 85 in-center patients, 59 from Wake County, leaving 38 Wake County patients and 21 patients from outside of Wake County at the beginning of 2019 after the transfer of 21 Wake County patients and five patients from outside of Wake County to Oak City dialysis upon its certification. The applicant further states that based on its calculations,

“Wake Forest Dialysis Center is projected to have at least 62 in-center patients by the end of operating year 1 for a utilization rate of 86.1% or 3.44 patients per station and at least 64 in-center patients by the end of operating year 2 for a utilization rate of 88.9% or 3.56 patients per station.”

Projected Utilization

The applicant’s in-center utilization methodology, based on its stated assumptions, is provided on page 18 and is summarized in the following table.

Start Date	# of SA Patients	x	Growth Factor	=	SA Year End Census	+	# Out of SA Patients	=	Total Year End Census	Year End Date
1/1/18	57	x	1.043	=	59.451	+	26	=	85.451	12/31/18
1/1/19	59-21 = 38	x	1.043	=	39.634	+	26-5 = 21	=	60.634	12/31/19
1/1/20	39.634	x	1.043	=	41.338	+	21	=	62.338	12/31/20
1/1/21	41.338	x	1.043	=	43.116	+	21	=	64.116	12/31/21

The applicant projects to serve 62 in-center patients (rounding down to the whole patient) or 3.4 patients per station per week ($62/18 = 3.44$) by the end of Operating Year 1 and 64 in-center patients or 3.6 patients per station per week ($64/18 = 3.56$) by the end of Operating Year 2 for the proposed 18-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 applicant's PD utilization methodology, based on its stated assumptions, is provided on page 19 and is summarized in the following table.

Start Date	# of Patients at Beginning of Year	Growth Factor	Total Year End Census
1/1/18	14	1 patient/year	15
1/1/19	15	1 patient/year	16
1/1/20	16	1 patient/year	17
1/1/21	17	1 patient/year	18

Projected utilization for dialysis patients at WFDC is reasonable and adequately supported for the following reasons:

- WFDC is currently operating at 94.32% capacity.
- The projection of the future utilization of services is based upon the facility's historical patient utilization, adjusted for all approved relocation of stations, transfer of patients, and addition of stations.
- The growth projections for in-center patients are based on an assumption that the Wake County dialysis in-center patient census will increase annually by 4.3%, which is consistent with the five-year AACR for Wake County, reported in the July 2018 SDR, Table D.
- Peritoneal dialysis patients are assumed to grow at the rate of one patient per year during the period of growth.

Access

In Section C.3, page 16, the applicant states:

“By policy, the proposed services will be made available to all residents in its service area without qualifications. The facility will serve patients without regard to race, sex, age, or handicap. We will serve patients regardless of ethnic or socioeconomic situation.

...

Payment will not be required upon admission. Therefore, services are available to all patients including low income persons, racial and ethnic minorities, women, handicapped person, elderly and other under-served persons.”

The applicant projects payor mix for the second operating year following completion of the project in Section L.1(b), page 46, by percent, as summarized below:

**Projected Payor Mix
OY2**

Payor Source	Total Patients	In-center Patients	HH Patients	PD Patients
Private Pay	0.0%	0.0%	0.0%	0.0%
Medicare	27.8%	29.9%	0.0%	15.4%
Medicaid	4.4%	5.2%	0.0%	0.0%
Commercial Insurance	5.6%	6.5%	0.0%	0.0%
Medicare / Commercial	43.3%	40.3%	0.0%	61.5%
Medicare / Medicaid	17.8%	16.8%	0.0%	23.1%
VA	1.1%	1.3%	0.0%	0.0%
Other	0.0%	0.0%	0.0%	0.0%
Total	100.0%	100.0%	0.0%	100.0%

Totals may not sum due to rounding

In Section L.1(b), page 46, the applicant states that the projected payor mix is based upon the sources of patient payments received by the existing facility during the last full operating year. The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- clarifying information requested by the Agency, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

- (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

The applicant does not propose a reduction or elimination of a service, or the relocation of a facility or a service; therefore, Criterion (3a) is not applicable to this review.

- (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

The applicant proposes to develop three additional dialysis stations for a total of 18 stations upon completion of this project, Project ID #J-11131-16 (relocate ten stations to Oak City Dialysis), Project ID #J-11152-16 (add one station), and Project ID #J-11254-16 (add two stations).

In Section E, page 23, the applicant describes the alternatives considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application. The alternatives considered were:

- Maintain status quo – the applicant states that this alternative was dismissed given the growth rate at the facility.
- Apply for three stations based on the facility need methodology – the applicant states this alternative meets the growing demand for services at WFDC.

On page 23, the applicant states that the project as proposed is the most effective alternative because it ensures that the facility will proactively address the issues of growth and access at the facility. The applicant further states:

“As calculated in Section B-2, there is a need for additional stations. ... We are committed to ensuring that all patients referred by our admitting nephrologists have convenient access to the facility and the chosen alternative does that effectively.”

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is 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 and any supplemental responses. In the event that representations conflict, Total Renal Care of North Carolina, LLC d/b/a Wake Forest Dialysis Center shall materially comply with the last made representation.

- 2. Pursuant to the facility need determination in the July 2018 SDR, Total Renal Care of North Carolina, LLC d/b/a Wake Forest Dialysis Center shall develop and operate no more than three additional dialysis stations for a total of no more than 18 certified stations upon completion of this project, Project I.D. #J-11131-16 (relocate 10 stations to Oak City Dialysis), Project I.D. #J-11152-16 (add 1 station), and Project I.D. #J-11254-16 (add 2 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 Agency 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

The applicant proposes to develop three additional dialysis stations for a total of 18 stations upon completion of this project, Project ID #J-11131-16 (relocate ten stations to Oak City Dialysis), Project ID #J-11152-16 (add one station), and Project ID #J-11254-16 (add two stations).

Capital and Working Capital Costs

In Section F.1, page 24, the applicant shows 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, because WFDC is an existing facility.

Financial Feasibility

The applicant provides pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Section R, 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.

Wake Forest Dialysis Center Revenue and Expenses		
	OY1 (CY2020)	OY2 (CY2021)
In-Center Average # of Patients*	61.0	63.0
In-Center Treatments	9,040	9,337
PD Average # of Patients*	16.5	17.5
PD Treatments	2,445	2,594
Gross Patient Revenue	\$3,214,314	\$3,334,676
Medicare Adjustment from Gross	\$141,828	\$146,897
Net Patient Revenue	\$3,072,486	\$3,187,779
Average Net Revenue per Patient	\$39,645	\$39,600
Total Operating Expenses	\$2,787,782	\$2,881,461
Average Operating Expense per Patient	\$35,971	\$35,795
Net Income	\$284,704	\$306,319

Totals may not sum due to rounding

*The applicant averages beginning and ending patient census for # of average patients per year to calculate OY1 and OY2 revenues.

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs, and charges. See Section R 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.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- clarifying information requested by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion because the applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

- (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 proposes to develop three additional dialysis stations for a total of 18 stations upon completion of this project, Project ID #J-11131-16 (relocate ten stations to Oak City Dialysis), Project ID #J-11152-16 (add one station), and Project ID #J-11254-16 (add two stations).

On page 365, the 2018 SMFP defines the service area for dialysis stations as “*the dialysis station 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.*” Wake Forest Dialysis Center is located in Wake County; thus, the service area for this facility consists of Wake County. Facilities may also serve residents of counties not included in their service area.

TRC (DaVita) is one of two providers of existing dialysis services in Wake County. According to the July 2018 SDR, Wake County has the following existing dialysis facilities operated by Fresenius Medical Care (FMC) and Davita.

Wake County Dialysis Facilities

Facility Name	Provider	Location	#of stations	Utilization
BMA of Fuquay-Varina Kidney Center	FMC	Fuquay-Varina	28	77.68%
BMA Raleigh Dialysis	FMC	Raleigh	50	91.50%
Cary Kidney Center	FMC	Cary	28	79.46%
FMC Apex	FMC	Apex	20	77.50%
FMC Central Raleigh	FMC	Raleigh	19	82.89%
FMC Eastern Wake	FMC	Rolesville	17	72.06%
FMC Millbrook	FMC	Raleigh	17	75.00%
FMC New Hope Dialysis	FMC	Raleigh	36	94.44%
FMC Northern Wake	FMC	Wake Forest	16	65.63%
Southwest Wake County Dialysis	FMC	Raleigh	30	97.50%
Wake Dialysis Clinic	FMC	Raleigh	50	94.50%
Wake Forest Dialysis Center	DaVita	Raleigh	22	94.32%
Zebulon Kidney Center	FMC	Zebulon	28	89.29%

Source: July 2018 SDR, Table B.

As shown in the table above, Wake Forest Dialysis Center is operating at 94.32% capacity. The table also shows that with the exception of one facility, the existing 13 Wake County facilities are all operating at above 72% capacity. In addition to the existing facilities listed above, the July 2018 SDR includes additional approved facilities consisting of existing stations from facilities listed above.

In Section G, pages 30-31, the applicant explains why it believes the proposal would not result in the unnecessary duplication of existing or approved dialysis services in Wake County. The applicant states that the application utilizes the facility need methodology and addresses the specific needs of patients who chose to receive service from DaVita. The applicant further states:

“In Section B-2 and Section C of this application, we demonstrate the need that Wake Forest Dialysis Center has for adding stations. While adding stations at this facility does increase the number of stations in Wake County, it is based on the facility need methodology. It ultimately serves to meet the needs of the facility’s growing population of patients referred by the facility’s admitting nephrologists.

The addition of stations, therefore, serves to increase capacity rather than duplicate any existing or approved services in the service area.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- The applicant demonstrates the need for the stations based on the Wake County DaVita facility’s patients’ needs.
- The applicant adequately demonstrates that the proposed stations are needed in addition to the existing stations in Wake County.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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

The applicant proposes to develop three additional dialysis stations for a total of 18 stations upon completion of this project, Project ID #J-11131-16 (relocate ten stations to Oak City Dialysis), Project ID #J-11152-16 (add one station), and Project ID #J-11254-16 (add two stations).

In Section H.1, page 32, the applicant provides current and projected OY2 staffing for the proposed services as summarized in the following table.

POSITION	Current FTE Positions	OY2 PROJECTED FTE POSITIONS
RN	3.0	3.0
LPN	0.0	0.0
Technician (Patient Care)	9.0	9.0
Medical Records	0.0	0.0
Administrator	1.0	1.0
Dietician	1.0	1.0
Social Worker	1.0	1.0
Home Training RN	1.0	1.0
Administrative Assistant	1.0	1.0
Bio-med Technician	0.5	0.5
Total	17.5	17.5

Source: Sections H and R of the application.

The assumptions and methodology used to project staffing are provided in Sections H and R. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in the pro forma financials found in Section R. In Section H, pages 33-34, the applicant describes the methods used to recruit or fill new positions and DaVita's existing training and continuing education programs. Exhibit H contains DaVita training documentation. The Medical Director is a contract service, not a full-time equivalent (FTE) position. In Section H.2, page 33, and Section I.3, page 38, the applicant identifies the Medical Director as Michael Oliverio, M.D. In Exhibit I-3, the applicant provides a letter from Dr. Oliverio indicating a commitment to continue to serve as Medical Director for the facility.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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

The applicant proposes to develop three additional dialysis stations for a total of 18 stations upon completion of this project, Project ID #J-11131-16 (relocate ten stations to Oak City Dialysis), Project ID #J-11152-16 (add one station), and Project ID #J-11254-16 (add two stations).

In Section I-1, pages 36-37, the applicant identifies the necessary ancillary and support services and explains how they will be made available. The applicant provides a table on page 36, as summarized below.

**North Burlington Dialysis
 Ancillary and Support Services**

Services	Provider
(a) In-center dialysis/maintenance	Available on Premises
(b) Self-care training (performed in-center)	Available on Premises
(c) Home training	
(1) Hemodialysis	Durham West Dialysis
(2) Peritoneal dialysis	Available on Premises
(3) Accessible follow-up program	Available on Premises
(d) Psychological counseling	Available on Premises
(e) Isolation-hepatitis	Available on Premises
(f) Nutritional counseling	Available on Premises
(g) Social work services	Available on Premises
(h) Acute dialysis in an acute care setting	WakeMed Health & Hospitals
(i) Emergency care	WakeMed Health & Hospitals
(j) Blood bank services	WakeMed Health & Hospitals
(k) Diagnostic and evaluation services	WakeMed Health & Hospitals
(l) X-ray services	WakeMed Health & Hospitals
(m) Laboratory services	DaVita Laboratory Services, Inc.
(n) Pediatric nephrology	WakeMed Health & Hospitals
(o) Vascular surgery	WakeMed Health & Hospitals
(p) Transplantation services	Duke University Medical Center
(q) Vocational rehabilitation counseling & services	NC Division of Vocational Rehabilitation Services
(r) Transportation	Wake Human Services

In Section I, pages 37-38, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation for some services in Exhibit I.

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.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that 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

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (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

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (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

The project does not require any construction or renovation; therefore, Criterion (12) is not applicable to this review.

- (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

The applicant proposes to develop three additional dialysis stations for a total of 18 stations upon completion of this project, Project ID #J-11131-16 (relocate ten stations to Oak City Dialysis), Project ID #J-11152-16 (add one station), and Project ID #J-11254-16 (add two stations).

In Section L.7, page 49, the applicant provides the historical (CY2017) payment source for the patients dialyzing at WFDC, as shown below.

Payment Source	Percent of Total Patients	Percent of IC Patients	Percent of PD Patients
Medicare	27.8%	29.9%	15.4%
Medicaid	4.4%	5.2%	0.0%
Commercial Insurance	5.6%	6.5%	0.0%
Medicare/Commercial	43.3%	40.3%	61.5%
Medicare/Medicaid	17.8%	16.8%	23.1%
VA	1.1%	1.3%	0.0%
Total	100.0%	100.0%	100.00%

The table above shows that more than 93% of the patients who received treatments at WFDC had some or all of their services paid for by Medicare or Medicaid in CY2017.

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 and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate
Wake	11%	51%	40%	9%	6%	9%
Statewide	16%	51%	37%	15%	10%	12%

Source: <http://www.census.gov/quickfacts/table/US/PST045217> Latest Data 7/1/17 as of 7/17/18

* Excludes "White alone, not Hispanic or Latino"

** "Estimates are not comparable to other geographic levels due to methodology differences that may exist between different data sources. 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., V2017) refers to the final year of the series (2010 thru 2017). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consisting of North Carolina, South Carolina and Georgia, provides an Annual Report which includes aggregate ESRD patient data from all three states. The report does not provide state-specific ESRD patient data, but the aggregate data is likely to be similar to North Carolina’s based on the Network’s recent annual reports which included state-specific data.

The IPRO SA Network 6 2016 Annual Report (pages 25-26¹) provides the following prevalence data on dialysis patients by age, race, and gender. As of December 31, 2016, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 66% were other than Caucasian and 45% were female.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the applicant adequately documents 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. Therefore, the application is conforming to this criterion.

¹<https://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/07/NW6-2016-Annual-Report-FINAL.pdf>

- (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

The applicant proposes to develop three additional dialysis stations for a total of 18 stations upon completion of this project, Project ID #J-11131-16 (relocate ten stations to Oak City Dialysis), Project ID #J-11152-16 (add one station), and Project ID #J-11254-16 (add two stations).

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.3(d), page 48, 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. The facility has no obligation under the Hill Burton Act.”

In Section L.6, page 48, the applicant states that there have been no civil rights access complaints filed against any similar facilities owned by the applicant or a related entity and located in North Carolina within the last five years.

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that 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

The applicant proposes to develop three additional dialysis stations for a total of 18 stations upon completion of this project, Project ID #J-11131-16 (relocate ten stations to Oak City Dialysis), Project ID #J-11152-16 (add one station), and Project ID #J-11254-16 (add two stations).

In Section L.1(b), page 46, the applicant projects the following payor mix for the proposed services during the second full calendar year of operation following completion of the project, as summarized in the table below.

**Projected Payor Mix
 OY2**

Payor Source	Total Patients	In-center Patients	HH Patients	PD Patients
Private Pay	0.00%	0.00%	0.00%	0.00%
Medicare	27.8%	29.9%	0.0%	15.4%
Medicaid	4.4%	5.2%	0.0%	0.0%
Commercial Insurance	5.6%	6.5%	0.0%	0.0%
Medicare / Commercial	43.3%	40.3%	0.0%	61.5%
Medicare / Medicaid	17.8%	16.8%	0.0%	23.1%
VA	1.1%	1.3%	0.0%	0.0%
Other	0.0%	0.0%	0.0%	0.0%
Total	100.0%	100.0%	0.0%	0.0%

Totals may not sum due to rounding

As shown in the table above, during the second full calendar year of operation, the applicant projects that 93.3% of the total dialysis patients will have all or part of their services paid for by Medicare and/or Medicaid.

On page 46, the applicant states that the projected payor mix is based on the sources of patient payments that have been received by the existing facility in the last full operating year. The projected payor mix is reasonable and adequately supported for the following reasons:

- the applicant bases the projected payor mix on the facility’s historical payor mix, and
- the applicant’s proposed patient origin is based on historical patient origin of the facility.

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that 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

The applicant proposes to develop three additional dialysis stations for a total of 18 stations upon completion of this project, Project ID #J-11131-16 (relocate ten stations to Oak City Dialysis), Project ID #J-11152-16 (add one station), and Project ID #J-11254-16 (add two stations).

In Section L.4, page 48, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that 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

The applicant proposes to develop three additional dialysis stations for a total of 18 stations upon completion of this project, Project ID #J-11131-16 (relocate ten stations to Oak City Dialysis), Project ID #J-11152-16 (add one station), and Project ID #J-11254-16 (add two stations).

In Section M, page 50, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-2.

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, 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 proposes to develop three additional dialysis stations for a total of 18 stations upon completion of this project, Project ID #J-11131-16 (relocate ten stations to Oak City Dialysis), Project ID #J-11152-16 (add one station), and Project ID #J-11254-16 (add two stations).

On page 365, the 2018 SMFP defines the service area for dialysis stations as “*the dialysis station 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.*” Wake Forest Dialysis Center is located in Wake County; thus, the service area for this facility consists of Wake County. Facilities may also serve residents of counties not included in their service area.

TRC (DaVita) is one of two providers of existing dialysis services in Wake County. According to the July 2018 SDR, Wake County has the following existing dialysis facilities.

Wake County Dialysis Facilities

Facility Name	Provider	Location	#of stations	Utilization
BMA of Fuquay-Varina Kidney Center	FMC	Fuquay-Varina	28	77.68%
BMA Raleigh Dialysis	FMC	Raleigh	50	91.50%
Cary Kidney Center	FMC	Cary	28	79.46%
FMC Apex	FMC	Apex	20	77.50%
FMC Central Raleigh	FMC	Raleigh	19	82.89%
FMC Eastern Wake	FMC	Rolesville	17	72.06%
FMC Millbrook	FMC	Raleigh	17	75.00%
FMC New Hope Dialysis	FMC	Raleigh	36	94.44%
FMC Northern Wake	FMC	Wake Forest	16	65.63%
Southwest Wake County Dialysis	FMC	Raleigh	30	97.50%
Wake Dialysis Clinic	FMC	Raleigh	50	94.50%
Wake Forest Dialysis Center	DaVita	Raleigh	22	94.32%
Zebulon Kidney Center	FMC	Zebulon	28	89.29%

Source: July 2018 SDR, Table B.

As shown in the table above, Wake Forest Dialysis Center is operating at 94.32% capacity. The table also shows that with the exception of one facility, the existing Wake County facilities are all operating at above 72% capacity. In addition to the existing facilities listed

above, the July 2018 SDR includes additional approved, non-operational facilities consisting of existing stations from facilities listed above.

In Section N, page 51, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. The applicant states:

“The expansion of Wake Forest Dialysis Center will have no effect on competition in Wake County. Although the addition of stations at this facility could serve to provide more patients another option to select a provider that gives them the highest quality service and better meets their needs, this project primarily 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 cost effectiveness of our services because it will make it easier for patients, family members and others involved in the dialysis process to receive services.”

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- the cost-effectiveness of the proposal (see Sections B, F, and R of the application and any exhibits),
- quality services will be provided (see Sections B and O of the application and any exhibits), and
- access will be provided to underserved groups (see Sections B and L of the application and any exhibits).

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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 Section A.11, page 5, the applicant states that DaVita operates over 85 dialysis facilities located in North Carolina. Exhibit A-11 contains a list of the facilities.

In Section O, page 52, the applicant refers to Exhibit O-3, which shows that during the 18-month look-back period immediately preceding the submittal of the application, incidents related to quality of care occurred in two of these DaVita facilities. On page 52, the applicant states that both facilities were back in compliance at the time of application submittal. After reviewing and considering information provided by the applicant and considering the quality of care provided at all 85 facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

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

C

The application is conforming with all applicable Criteria and Standards for End-Stage Renal Disease Services. The specific criteria are discussed below.

SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES

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 18, the applicant projects to serve 62 in-center patients by the end of Operating Year 1, which is 3.7 patients ($62 / 18 = 3.44$) per station per week, exceeding the required 3.2 patients per station per week. 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.7, pages 17-19, 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.