

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 17, 2019

Findings Date: December 17, 2019

Project Analyst: Celia C. Inman

Team Leader: Fatimah Wilson

Project ID #: J-11778-19

Facility: Southwest Wake County Dialysis

FID #: 990968

County: Wake

Applicant: Bio-Medical Applications of North Carolina, Inc.

Project: Add no more than 4 dialysis stations for a total of no more than 30 stations upon completion of this project, Project ID #J-11739-19 (relocate 4 stations to FKC West Johnston), Project ID #J-11661-19 (add 2 stations) and Project ID #J-11510-18 (relocate 2 stations to FKC Holly Springs)

### 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

Bio-Medical Applications of North Carolina, Inc. (hereinafter referred to as “the applicant” or BMA) proposes to add four dialysis stations to the existing Southwest Wake County Dialysis facility for a total of no more than 30 dialysis stations upon completion of this project, Project ID #J-11739-19 (relocate four stations to FKC West Johnston), Project ID #J-11661-19 (add two stations) and Project ID #J-11510-18 (relocate two stations to FKC Holly Springs).

**Need Determination**

The 2019 State Medical Facilities Plan (2019 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table D, page 64, in the July 2019 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of 15 stations in Wake County; therefore, there is no county need determination for new dialysis stations for Wake County.

However, the applicant is eligible to apply for additional dialysis stations in an existing facility based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. The utilization rate reported for Southwest Wake County Dialysis in the July 2019 SDR is 3.80 patients per station per week, or 95%, based on 114 in-center dialysis patients and 30 certified dialysis stations [ $114 / 30 = 3.8$ ;  $3.8 / 4 = 0.9500$ ]. Therefore, Southwest Wake County Dialysis is eligible to apply for additional stations based on the facility need methodology.

Application of the facility need methodology indicates up to five additional stations may be needed at this facility, as illustrated in the following the table:

<b>Southwest Wake County Dialysis</b>		
<b>OCTOBER 1 REVIEW-JULY 2019 SDR</b>		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/18		95.00%
Certified Stations		30
Pending Stations		2
<b>Total Existing and Pending Stations</b>		<b>32</b>
In-Center Patients as of 12/31/18 (July 2019 SDR) (SDR2)		114
In-Center Patients as of 6/30/18 (January 2019 SDR) (SDR1)		112
Step	Description	Result
	Difference (SDR2 - SDR1)	2
(i)	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 6/30/18	0.0357
(ii)	Divide the result of Step (i) by 12	0.0030
(iii)	Multiply the result of Step (ii) by 12	0.0357
(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	118.0714
(v)	Divide the result of Step (iv) by 3.2 patients per station	36.8973
	and subtract the number of certified and pending stations to determine the number of stations needed	4.8973

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed at Southwest Wake County Dialysis is five stations, based

on rounding allowed in Step (v). 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 four new stations; therefore, the application is consistent with the facility need determination for dialysis stations.

### **Policies**

There is one policy in the 2019 SMFP which is applicable to this review. Policy GEN-3: Basic Principles, on page 31 of the 2019 SMFP, is applicable to this review because the facility need methodology is applicable to this review. Policy GEN-3 states:

*“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”*

### **Promote Safety and Quality**

The applicant describes how it believes the proposed project will promote safety and quality in Section B.3 (a and d), pages 12 and 14, respectively; Section N.2(b), page 55; Section O, pages 57-60; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote safety and quality.

### **Promote Equitable Access**

The applicant describes how it believes the proposed project will promote equitable access in Section B.3 (b and d), pages 12-13 and 14, respectively; Section C.7, pages 21-22; Section L, pages 49-52; Section N.2(c), page 55; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote equitable access.

### **Maximize Healthcare Value**

The applicant describes how it believes the proposed project will maximize healthcare value in Section B.3 (c and d), pages 13-14; Section N.2(a), page 55; and referenced exhibits. The information provided by the applicant with regard to its efforts to maximize healthcare value is reasonable and supports the determination that the applicant’s proposal will maximize healthcare value.

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

### **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.

- (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 add four dialysis stations for a total of 30 dialysis stations upon completion of this project, Project ID #J-11739-19 (relocate four stations to FKC West Johnston), Project ID #J-11661-19 (add two stations) and Project ID #J-11510-18 (relocate two stations to FKC Holly Springs).

The following table, summarized from data on page 7 of the application and Table B of the July 2019 SDR, illustrates the current and projected number of dialysis stations at Southwest Wake County Dialysis.

**Southwest Wake County Dialysis**

# of Stations	Description	Project ID #
30	Total # of existing certified stations as reported in the SDR in effect on the day the review will begin	
4	# of stations to be added as part of this project	J-11778-19
	# of stations to be deleted as part of this project	
2	# of stations previously approved to be added but not yet certified	J-11661-19
-2	# of stations previously approved to be deleted but not yet certified	J-11510-18
	# of stations proposed to be added in an application still under review	
-4	# of stations proposed to be deleted in an application still under review	J-11739-19
30	Total # of stations upon completion of all facility projects	

As outlined in the table above, in this application, the applicant proposes to add four dialysis station for a total of 30 stations upon the completion of the projects as outlined above.

**Patient Origin**

On page 369, the 2019 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.*” Thus, the service area for this facility is Wake County. Facilities may serve residents of counties not included in their service area.

In Section C.2, page 17, the applicant provides the patient origin for in-center patients at Southwest Wake County Dialysis as of December 31, 2018, as summarized in the table below. The facility does not provide home therapy dialysis.

**Southwest Wake County Dialysis  
 1/1/2018 -12/31/2018**

COUNTY	# of Patients	% of Total
Wake	111.0	97.37%
Durham	1.0	0.88%
Johnston	2.0	1.75%
<b>Total</b>	<b>114.0</b>	<b>100.00%</b>

Totals may not sum due to rounding

The following table summarizes projected patient origin for the second full operating year following project completion, as provided in Section C, page 17.

**Southwest Wake County Dialysis  
Projected Patient Origin  
OY2 CY2022**

COUNTY	# of Patients	% of Total
Wake	113.9	100.0%
<b>Total</b>	<b>113.9</b>	<b>100.0%</b>

Totals may not sum due to rounding

In Section C, pages 18-19, the applicant provides the assumptions and methodology it used to project patient origin. The applicant states that the patient origin is based upon the June 30, 2019 facility information submitted to the Agency in August 2019 and provided on page 18 of the application. The applicant's assumptions are reasonable and adequately supported.

**Analysis of Need**

The applicant proposes to add four dialysis stations for a total of 30 dialysis stations upon completion of this project and the related projects previously approved.

In Section Q, pages 69-70, the applicant describes its need methodology and assumptions for projecting in-center utilization of the facility, summarized as follows:

- The applicant states that it projects patients forward from the June 30, 2019 census data, which the applicant states was submitted to the Agency on the ESRD Data Collection form in August 2019. The applicant provides a table on page 69 that shows the facility census as of December 31, 2018 and June 30, 2019, as summarized below.

**Southwest Wake County Dialysis  
In-Center Patients**

COUNTY	12/31/2018	6/30/2019
Wake	111	112
Durham	1	0
Johnston	2	2
<b>Total</b>	<b>114</b>	<b>114</b>

- The applicant states that it assumes the patients from Wake County dialyzing at Southwest Wake County Dialysis on June 30, 2019 will continue to dialyze there and will increase at a rate equal to the 3.6% Wake County Five Year Average Annual Change Rate (AACR) published in the July 2019 SDR.
- The applicant states that BMA has three other projects that project the transfer of patients from Southwest Wake County Dialysis, as of December 31, 2020, as shown on page 70 and below.

PROJECT ID	NAME OF FACILITY	ESTIMATED CERTIFICATION	# OF PATIENTS TO TRANSFER
J-11271-16	FMC Rock Quarry	12/31/2020	8 Wake County patients
J-11435-17	FKC West Johnston	12/31/2020	3 Johnston County patients
J-11738-19	FMC White Oak	12/31/2020	4 Wake County patients

The applicant states the Wake County patients, as shown above, will be subtracted from the projected census of Southwest Wake County Dialysis.

- Services will be offered as of December 31, 2020. Therefore, Operating Year (OY) 1 is calendar year (CY) 2021, January 1-December 31, 2021 and OY2 is CY2022, January 1-December 31, 2022.

Projected Utilization

In Section Q, page 70, the applicant provides its projected utilization methodology, based on its stated assumptions. The projected utilization is summarized in the following table.

<b>SOUTHWEST WAKE COUNTY DIALYSIS IN-CENTER PATIENTS</b>	
Begin with facility census of Wake County patients as of June 30, 2019.	112.0
Project Wake County population forward six months to December 31, 2019, using the Wake County Five Year AACR of 3.6%. (3.6% / 12 x 6 = 1.8%)	$112 \times 1.018 = 114.0$
Project this population forward one year to December 31, 2020, using the Wake County AACR of 3.6%.	$114.0 \times 1.036 = 118.1$
Subtract 12 Wake County patients projected to transfer as of December 31, 2020. The Johnston County patients do not need to be subtracted because they are not included in the Wake County patient projections. This is the ending census December 31, 2021.	$118.1 - 12 = 106.1$
Project the Wake County population forward one year to December 31, 2021, using the Wake County AACR of 3.6%. This is the ending census on December 31, 2021.	$106.1 \times 1.036 = 109.9$
Project Wake County population forward one year to December 31, 2022, using the Wake County AACR of 3.6%. This is the ending census on December 31, 2022.	$109.9 \times 1.036 = 113.9$

Source: Table in Section Q, page 70  
 Totals may not sum due to rounding

At the end of OY1 (CY2021) Southwest Wake County Dialysis is projected to serve 109.9 in-center patients on 30 stations; and at the end of OY2 (CY2022) the facility is projected to serve 113.9 in-center patients on 30 stations.

The projected utilization rates for the first two operating years are as follows:

- OY1: 3.66 patients per station per week, or 91.6% utilization [ $109.9 / 30 = 3.66$ ;  $3.66 / 4 = 0.9158$ ].
- OY 2: 3.79 patients per station per week, or 94.9% utilization [ $113.9$  patients /  $30$  stations =  $3.79$ ;  $3.79 / 4 = 0.9491$ ].

The projected utilization of 3.66 patients per station per week at the end of OY1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

Projected utilization is reasonable and adequately supported for the following reasons:

- Southwest Wake County Dialysis was operating at 95% capacity as of December 31, 2018, as reported in the July 2019 SDR.
- The applicant projects growth in the Wake County patient population using the Wake County Five Year AACR of 3.6%, as published in the July 2019 SDR.
- The applicant subtracts the patients projected to transfer to other facilities upon completion of several proposed projects.
- Projected IC utilization at the end of OY1 exceeds the minimum of 3.2 patients per station per week required by 10A NCAC 14C .2203(b).

Projected utilization at Southwest Wake County Dialysis is reasonable and adequately supported for the reasons stated above.

### Access

In Section C.7, pages 21-22, the applicant states:

*“Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.*

*It is corporate policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.*

*Fresenius related facilities in North Carolina have historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for being an underserved person.”*

In Section L, page 51, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as summarized in the following table.



**Southwest Wake County Dialysis  
Projected Payor Mix CY 2022**

Payment Source	In-Center Dialysis	
	# of Patients	% of Total
Self-pay	3.45	3.03%
Commercial Insurance*	5.67	4.97%
Medicare*	44.72	39.27%
Medicaid*	18.42	16.17%
Medicare/Commercial	33.48	29.39%
Miscellaneous (Incl. VA)	8.16	7.17%
<b>Total</b>	<b>113.90</b>	<b>100.00%</b>

Totals may not sum due to rounding

\*Including any managed care plans

The projected payor mix is reasonable and adequately supported.

**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 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, elimination or relocation of a facility or 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 add four dialysis stations for a total of 30 dialysis stations upon completion of this project, Project ID #J-11739-19 (relocate four stations to FKC West Johnston), Project ID #J-11661-19 (add two stations) and Project ID #J-11510-18 (relocate two stations to FKC Holly Springs).

In Section E, pages 27-28, the applicant states it considered the following alternatives to serve the needs of the patients in the area:

1. Maintain the status quo – the applicant states that this alternative fails to recognize the growth of the ESRD patient population residing in the area of the BMA Southwest Wake facility. The applicant states that failure to add stations will have an adverse impact on admissions to the facility and that it is necessary to add four stations to ensure an adequate station capacity for the patients of the area.
2. Relocate stations from a BMA facility in Wake County – the applicant lists multiple facilities from which stations could be relocated and states that those Fresenius related facilities are well utilized and relocating stations would only serve to increase the utilization rate of the facilities and potentially impede access to care by other patients who might desire to dialyze at the facility. Additionally, the methodology fails to produce replacement stations at some of the facilities and at the ones where the methodology does produce additional stations, they are needed at the facility. The applicant states that relocating stations from these facilities would be inappropriate under the existing circumstances listed with each facility, as discussed on pages 27-28.

On page 29, the applicant states that after considering the above alternatives, it elected to add four stations because this proposal is the most cost-effective approach to providing the necessary services for the patient population projected to be served at Southwest Wake County Dialysis.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provided credible information to explain why it believes the proposed project is the most effective alternative.

## **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. Therefore, the application is approved subject to the following conditions:

- 1. Bio-Medical Applications of North Carolina, Inc. shall materially comply with all representations made in the certificate of need application.**
  - 2. Pursuant to the facility need determination in the July 2019 SDR, Bio-Medical Applications of North Carolina, Inc. shall develop no more than four additional dialysis stations at Southwest Wake County Dialysis for a total of no more than 30 certified stations upon completion of this project, Project ID #J-11739-19 (relocate four stations to FKC West Johnston), Project ID #J-11661-19 (add two stations) and Project ID #J-11510-18 (relocate two stations to FKC Holly Springs), which shall include any home hemodialysis training or isolation stations.**
  - 3. Bio-Medical Applications of North Carolina, Inc. 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 add four dialysis stations for a total of 30 dialysis stations upon completion of this project, Project ID #J-11739-19 (relocate four stations to FKC West Johnston), Project ID #J-11661-19 (add two stations) and Project ID #J-11510-18 (relocate two stations to FKC Holly Springs).

## **Capital and Working Capital Costs**

In Section F.1(a), the applicant states that there are no capital costs associated with the proposed project. Section Q Form F.1a Capital Cost, page 72, shows no capital cost is projected for this project.

In Section F.3, pages 31-32, the applicant states there will be no start-up or initial operating expenses associated with the proposed project since this is an existing facility that is already operational.

### **Financial Feasibility**

The applicant provides pro forma financial statements for the first two full operating years following completion of the project. In Section Q Form F.2 Income Statement, page 75, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as summarized in the table below.

**Southwest Wake County Dialysis  
Projected Revenue and Operating Expenses**

	<b>OY 1 CY2021</b>	<b>OY 2 CY2022</b>
Total Treatments (IC, HH, and PD)	15,988.55	16,564.14
Total Gross Revenue (charges)	\$100,583,971	\$104,204,994
Total Net Revenue	\$4,267,520	\$4,421,151
Average Net Revenue per Treatment	\$266.91	\$266.91
Total Operating Expenses (costs)	\$3,897,565	\$4,013,707
Average Operating Expense per Treatment	\$243.77	\$242.31
<b>Net Income / Profit</b>	<b>\$369,954</b>	<b>\$407,443</b>

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

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 add four dialysis stations for a total of 30 dialysis stations upon completion of this project, Project ID #J-11739-19 (relocate four stations to FKC West Johnston), Project ID #J-11661-19 (add two stations) and Project ID #J-11510-18 (relocate two stations to FKC Holly Springs).

On page 369, the 2019 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.*” Thus, the service area is Wake County. Facilities may serve residents of counties not included in their service area.

The applicant operates 14 dialysis centers in Wake County. Also, BMA has been approved to develop two additional facilities in Wake County, FKC Holly Springs and FMC Rock Quarry, but the facilities were not yet operational on December 31, 2018. DaVita is the only other provider of dialysis services in Wake County, and currently operates Wake Forest Dialysis, and has been approved to develop Oak City Dialysis. See the following table that shows the existing and approved dialysis facilities in Wake County, from Table B of the July 2019 SDR.

**Wake County Dialysis Facilities**

Dialysis Facility	Certified Stations 12/31/18	CON Issued Not Certified	% Utilization	Patients Per Station
BMA of Fuquay-Varina Kidney Center (BMA)	28	0	84.82%	3.3929
BMA of Raleigh Dialysis (BMA)	50	0	90.50%	3.6200
Cary Kidney Center (BMA)	24	0	89.58%	3.5833
FMC Eastern Wake (BMA)	17	0	64.71%	2.5882
FMC Morrisville (BMA)	10	0	45.00%	1.8000
FMC New Hope Dialysis (BMA)	36	0	86.11%	3.4444
FMC Northern Wake (BMA)	14	0	87.50%	3.5000
Wake Dialysis Clinic (BMA)	50	0	98.50%	3.9400
FKC Holly Springs (BMA)	0	10	NA	NA
FMC Apex (BMA)	20	0	82.50%	3.3000
FMC Central Raleigh (BMA)	19	0	67.11%	2.6842
FMC Millbrook (BMA)	17	0	76.47%	3.0588
FMC Rock Quarry (BMA)	0	10	NA	NA
FMC White Oak (BMA)	12	0	62.50%	2.5000
Oak City Dialysis (DaVita)	0	10	NA	NA
Southwest Wake County Dialysis (BMA)	30	-2	95.00%	3.8000
Wake Forest Dialysis Center (DaVita)	22	-4	98.86%	3.9545
Zebulon Kidney Center (BMA)	30	-4	86.67%	3.4667

Source: July 2019 SDR, Table B.

In Section G, pages 35-36, the applicant provides the Wake County BMA facility utilization for the periods that ended December 31, 2018 and June 30, 2019. The applicant states that the June 30, 2019 data was submitted to the Agency on the ESRD Data Collection form in August 2019. In Section G, page 37, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Wake County. The applicant states:

*“This is an application to add four stations, [sic] to BMA Southwest Wake.*

*The July 2019 SDR does report a surplus of 15 dialysis stations in Wake County. The SDR also reports that the Wake County ESRD Census for December 31, 2018 was 1,388, and that this census was increasing at a rate of 3.6%. The growth of the Wake County ESRD patient population results in a projection of 49.8 new dialysis patients for 2019. If this growth rate is sustained, (and there is no indication that the growth rate will not be sustained), and assuming the home patient population percentage remains the same, Wake County will need 13 new dialysis stations each year (at 80% utilization; 14 new stations at 75% utilization). The current surplus of stations will be quickly eroded.*

*Approval of this application [sic] not cause unnecessary duplication of services, but will ensure an adequate inventory of dialysis stations exists for the ESRD patient population of the county.”*

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

- There is a facility need determination at Southwest Wake County Dialysis, as calculated using the methodology in the July 2019 SDR, for the proposed additional dialysis stations.
- The applicant adequately demonstrates that the proposed dialysis stations are needed in addition to the existing or approved additional dialysis stations.

### **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

In Section Q Form H Staffing, page 83, the applicant provides a table showing current and projected staffing in full time equivalent (FTE) positions for Southwest Wake County Dialysis, as summarized below.

POSITION	FTE Positions as of 6/30/19	FTE POSITIONS OY1	FTE POSITIONS OY2
FMC Clinic Manager	1.00	1.00	1.00
RN	4.00	4.00	4.00
LPN	2.00	2.00	2.00
Patient Care Technician	10.00	10.00	10.00
Dietician	1.00	1.00	1.00
Social Worker	1.00	1.00	1.00
Equipment Technician	1.00	1.00	1.00
Administration	1.00	1.00	1.00
FMC Director Operations	0.15	0.15	0.15
In-Service	0.20	0.20	0.20
Chief Technician	0.15	0.15	0.15
<b>Total</b>	<b>21.50</b>	<b>21.50</b>	<b>21.50</b>

Source: Section Q Form H

The assumptions and methodology used to project existing staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.4 Operating Costs. In Section H, page 39, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. Exhibit H contains documentation of its continuing education programs. In Section H.4, page 40, the applicant identifies the current medical director for the facility as Dr. Michael Casey. In Exhibit H-4, the applicant provides a letter from Michael J. Casey, MD indicating his intent to continue to serve as medical director for the proposed services.

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

In Section I, page 42, the applicant states that the following ancillary and support services are necessary for the proposed services, and explains how each ancillary and support service is made available:

<b>ANCILLARY AND SUPPORT SERVICES</b>	
<b>SERVICES</b>	<b>PROVIDER</b>
Self-care training	Referral to Wake Dialysis Clinic
Home training HH PD Accessible follow-up program	Referral to Wake Dialysis Clinic
Psychological counseling	Referral to Alliance Behavioral Health
Isolation – hepatitis	BMA on site
Nutritional counseling	BMA on site
Social Work services	BMA on site
Acute dialysis in an acute care setting	Referral to Rex Hospital or WakeMed
Emergency care	BMA staff until ambulance transport to hospital
Blood bank services	Referral to Rex Hospital
Diagnostic and evaluation services	Referral to Rex Hospital or WakeMed
X-ray services	Referral to Rex Hospital or WakeMed
Laboratory services	BMA on site / Spectra
Pediatric nephrology	Referral to UNC Healthcare
Vascular surgery	Rex Hospital; Raleigh Access Center; Wake Vascular Surgery, or Triangle Vascular
Transplantation services	Referral to UNC Healthcare
Vocational rehabilitation & counseling	Referral to Wake County Vocational Rehabilitation Services
Transportation	Go Wake transportation services

Source: Table in Section I, page 42

In Section I, page 42, the applicant describes its existing and proposed relationships with other local health care and social service providers. In Exhibit I, the applicant provides supporting documentation for established relationships with local health care providers and for referrals.

The applicant adequately demonstrates 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 applicant does not propose 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

In Section L, page 50, the applicant provides the historical payor mix for Southwest Wake County Dialysis patients during CY2018 for its existing services, as shown in the table below.

**Southwest Wake County Dialysis  
Historical Payor Mix CY2018**

Payment Source	In-Center Dialysis	
	# of Patients	% of Total
Self-pay	3.45	3.03%
Commercial Insurance*	5.67	4.97%
Medicare*	44.76	39.27%
Medicaid*	18.44	16.17%
Medicare/Commercial	33.51	29.39%
Miscellaneous (Incl. VA)	8.17	7.17%
<b>Total</b>	<b>114.00</b>	<b>100.00%</b>

Totals may not sum due to rounding  
\*Including any managed care plans

In Section L.1(a), page 49, the applicant provides comparison of the demographical information on Southwest Wake County Dialysis patients and the service area patients during CY2018, as summarized below.

	Percentage of Total Patients Served during the Last Full OY	Percentage of the Population of the Service Area*
Female	45.4%	51.3%
Male	54.6%	48.7%
Unknown		
64 and Younger	64.8%	88.4%
65 and Older	35.2%	11.6%
American Indian	0.0%	0.8%
Asian	0.0%	7.5%
Black or African-American	75.9%	21.0%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	11.1%	59.8%
Other Race	13.0%	10.8%
Declined / Unavailable	0.0%	

\* The percentages can be found online using the United States Census Bureau’s QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>. Just enter in the name of the 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 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.

- (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

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, the applicant states in Section L, page 50, that it has no obligation in any of its facilities to provide uncompensated care, community service, or access by minorities and handicapped persons.

In Section L, page 51, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

**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.

- (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, page 51, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as summarized in the following table.

**Southwest Wake County Dialysis  
Projected Payor Mix CY 2022**

Payment Source	In-Center Dialysis	
	# of Patients	% of Total
Self-pay	3.45	3.03%
Commercial Insurance*	5.67	4.97%
Medicare*	44.72	39.27%
Medicaid*	18.42	16.17%
Medicare/Commercial	33.48	29.39%
Miscellaneous (Incl. VA)	8.16	7.17%
<b>Total</b>	<b>113.90</b>	<b>100.00%</b>

Totals may not sum due to rounding

\*Including any managed care plans

As shown in the table above, in the second full year of operation, the applicant projects that 3.03% of in-center dialysis services will be provided to self-pay patients, 68.66% to Medicare patients (includes Medicare and Medicare/Commercial), and 16.17% to Medicaid patients.

On pages 51-52, the applicant provides the assumptions and methodology it uses to project payor mix during the second full year of operation following completion of the project, stating the payor mix is based upon recent facility history of actual treatment volumes. The applicant explains that Fresenius reports payor source of treatments, not whole patients as requested in the table, which the applicant states provides a clear indication of the source of revenue.

The projected payor mix is reasonable and adequately supported because the projected payor mix is based on the historical payor mix of Southwest Wake County Dialysis.

**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.

- (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, page 52, the applicant adequately describes the range of means by which patients will have access to 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.

- (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, page 53, 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.

**Conclusion**

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 add four dialysis stations for a total of 30 dialysis stations upon completion of this project, Project ID #J-11739-19 (relocate four stations to FKC West Johnston), Project ID #J-11661-19 (add two stations) and Project ID #J-11510-18 (relocate two stations to FKC Holly Springs).

On page 369, the 2019 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.*” Thus, the service area is Wake County. Facilities may serve residents of counties not included in their service area.

The applicant operates 14 dialysis centers in Wake County. Also, BMA has been approved to develop two additional facilities in Wake County, FKC Holly Springs and FMC Rock Quarry but the facilities were not yet operational on December 31, 2018. DaVita is the only other provider of dialysis services in Wake County, and currently operates Wake Forest Dialysis, and has been approved to develop Oak City Dialysis. See the following table that shows the existing and approved dialysis facilities in Wake County, from Table B of the July 2019 SDR.

**Wake County Dialysis Facilities**

Dialysis Facility	Certified Stations 12/31/18	CON Issued Not Certified	% Utilization	Patients Per Station
BMA of Fuquay-Varina Kidney Center (BMA)	28	0	84.82%	3.3929
BMA of Raleigh Dialysis (BMA)	50	0	90.50%	3.6200
Cary Kidney Center (BMA)	24	0	89.58%	3.5833
FMC Eastern Wake (BMA)	17	0	64.71%	2.5882
FMC Morrisville (BMA)	10	0	45.00%	1.8000
FMC New Hope Dialysis (BMA)	36	0	86.11%	3.4444
FMC Northern Wake (BMA)	14	0	87.50%	3.5000
Wake Dialysis Clinic (BMA)	50	0	98.50%	3.9400
FKC Holly Springs (BMA)	0	10	NA	NA
FMC Apex (BMA)	20	0	82.50%	3.3000
FMC Central Raleigh (BMA)	19	0	67.11%	2.6842
FMC Millbrook (BMA)	17	0	76.47%	3.0588
FMC Rock Quarry (BMA)	0	10	NA	NA
FMC White Oak (BMA)	12	0	62.50%	2.5000
Oak City Dialysis (DaVita)	0	10	NA	NA
Southwest Wake County Dialysis (BMA)	30	-2	95.00%	3.8000
Wake Forest Dialysis Center (DaVita)	22	-4	98.86%	3.9545
Zebulon Kidney Center (BMA)	30	-4	86.67%	3.4667

Source: July 2019 SDR, Table B.

According to Table D in the July 2019 SDR, there is a surplus of 15 dialysis stations in Wake County. The applicant proposes to add four dialysis stations to the existing facility in Wake County pursuant to the facility need determination methodology.

In Section N, pages 54-56, 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 applicant does not expect this proposal to have any effect on the competitive climate in Wake County. The applicant does not project to serve dialysis patients currently being served by another provider. The projected patient population for the BMA Southwest Wake facility begins the current patient population.*

...

*Fresenius related facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid.*

...

*Fresenius related facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients.*



...

*Fresenius Medical Care, parent organization for this facility, expects every facility to provide high quality care to every patient at every treatment.*

...

*It is corporate policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.”*

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 Q of the application and any exhibits).
- Quality services will be provided (see Sections B and O of the application and any exhibits).
- Access will be provided to underserved groups (see Sections B and L of the application and any exhibits).

### **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.

- (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 Q Form A Facilities, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies 127 dialysis facilities owned, operated, or managed by the applicant or a related entity located in North Carolina.

In Section O, page 60, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care that resulted in a finding

of “*Immediate Jeopardy*” occurred in any of these facilities. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all Fresenius facilities, the applicant provides 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 Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The application is conforming to all applicable criteria, as discussed below.

#### **10 NCAC 14C .2203 PERFORMANCE STANDARDS**

(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- Southwest Wake County Dialysis is an existing facility.

(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 Q Form C, page 68, the applicant projects that Southwest Wake County Dialysis will serve 109.9 in-center patients on 30 stations, or a rate of 3.66 patients per station per week, as of the end of the first operating year following project completion. This exceeds the minimum performance standard of 3.2 patients per station per week. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

- (c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
  
- C- In Section Q, pages 69-70, the applicant provides the assumptions and methodology it used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.