

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 21, 2019

Findings Date: June 21, 2019

Project Analyst: Mike McKillip

Team Leader: Fatimah Wilson

Project ID #: J-11661-19

Facility: Southwest Wake County Dialysis

FID #: 990968

County: Wake

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

Project: Add no more than two dialysis stations for a total of no more than 30 dialysis stations upon completion of this project and Project I.D. # J-11510-18 (relocate two dialysis 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. (BMA) proposes to add no more than two dialysis stations to Southwest Wake County Dialysis for a total of no more than 30 dialysis stations at the facility upon completion of this project and Project I.D. # J-11510-18 (relocate two dialysis stations to FKC Holly Springs).

#### **Need Determination**

The 2019 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 January 2019 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of 22 dialysis stations in Wake County. Therefore, the January 2019 SDR does not indicate a need for additional stations in Wake County based on the county need methodology.

However, the applicant is eligible to apply for additional dialysis stations 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 percent. The utilization rate reported for Southwest Wake County Dialysis in the January 2019 SDR is 3.73 patients per station per week, or 93.33 percent, based on 112 in-center dialysis patients and 30 certified dialysis stations [ $112 / 30 = 3.73$ ;  $3.73 / 4 = 0.9333$  or 93.33%].

Application of the facility need methodology indicates that up to a potential maximum of 4 additional stations are needed for this facility, as illustrated in the following table.

<b>APRIL 1 REVIEW – JANUARY 2019 SDR</b>		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/18		93.33%
Certified Stations		30
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>30</b>
In-Center Patients as of 6/30/18 (January 2019 SDR) (SDR2)		112
In-Center Patients as of 12/31/17 (July 2018 SDR) (SDR1)		117
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	-5
	Multiply the difference by 2 for the projected net in-center change	-10
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/17	-0.0855
(ii)	Divide the result of Step (i) by 12	-0.0071
(iii)	Multiply the result of Step (ii) by 6 (the number of months from 6/30/18 until 12/31/18)	-0.0427
(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	107.2137
(v)	Divide the result of Step (iv) by 3.2 patients per station	33.5043
	and subtract the number of certified and pending stations to determine the number of stations needed	<b>4</b>

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is four stations. Rounding to the nearest whole number is allowed in Step (v) of the facility need methodology, as stated in the January 2019 SDR. Step (C) of the facility need methodology states, “*The facility may apply to expand to meet the need established ..., up to a maximum of ten stations.*” The applicant proposes to add two new stations and is therefore 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, page 8; Section K, pages 43-44; Section N, pages 54-55; Section O, pages 56-58; 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, page 9; Section C, page 15; Section L, pages 48-50; Section N, pages 54-55; 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, page 10; Section C, pages 13-14; Section F, pages 24-30; Section K, pages 43-46; Section N, pages 54-55; 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
- 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 no more than two dialysis stations to Southwest Wake County Dialysis for a total of no more than 30 dialysis stations at the facility upon completion of this project and Project I.D. # J-11510-18 (relocate two dialysis stations to FKC Holly Springs).

**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 is Wake County. Facilities may serve residents of counties not included in their service area.

The following table illustrates current and projected patient origin.

<b>Southwest Wake County Dialysis Current and Projected Patient Origin</b>						
<b>County</b>	<b>Current (12/31/2018)</b>		<b>Projected OY 1 (CY2020)</b>		<b>Projected OY 2 (CY2021)</b>	
	<b># Patients</b>	<b>% of Total</b>	<b># Patients</b>	<b>% of Total</b>	<b># Patients</b>	<b>% of Total</b>
Wake	111	97.4%	117.2	100.0%	122.3	100.0%
Durham	1	0.8%	0	0.0%	0	0.0%
Johnston	2	1.8%	0	0.0%	0	0.0%
<b>Total</b>	<b>114</b>	<b>100.0%</b>	<b>117</b>	<b>100.0%</b>	<b>122</b>	<b>100.0%</b>

Source: Section C, pages 13 and 17

Southwest Wake County Dialysis does not currently offer either home hemodialysis training or home peritoneal dialysis training and does not plan to offer either home hemodialysis training or home peritoneal dialysis training following completion of the proposed project.

In Section C, pages 13-14, the applicant provides the assumptions and methodology it used to project patient origin. The applicant’s assumptions are reasonable and adequately supported.

**Analysis of Need**

In Section C, pages 14-15, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

*“Patients with End Stage Renal Disease require dialysis treatment on a regular and consistent basis in order to maintain life. As a general rule, patients will receive three treatments per week. The NC SMFP recognizes that this patient population requires frequent and regular treatment. ... Failure to receive dialysis care will ultimately lead to the patient’s demise.*

*In this application, BMA has projected a patient population of 117 patients to be dialyzing at the Southwest Wake County Dialysis facility at the end of the first year. Failure to add this additional station will lead to higher utilization rates at the facility.”*

Additionally, in Section B, page 6, the applicant demonstrates the need for the proposed project using the facility need methodology.

The information is reasonable and adequately supported for the following reasons:

- Southwest Wake County Dialysis is currently operating at a rate of 3.733 patients per station per day, or 93.33 percent of capacity.
- The applicant demonstrates eligibility to add dialysis stations to its facility via the facility need methodology. The discussion regarding need methodology found in Criterion (1) is incorporated herein by reference.

#### Projected Utilization

In Section C, pages 13-14, the applicant provides the assumptions and methodology it used to project utilization, which are summarized below.

- The applicant begins its utilization projections by using its facility census as of December 31, 2018.
- The applicant assumes that the patient population currently receiving treatment at Southwest Wake County Dialysis and who currently reside in Wake County will increase annually at a rate of 4.3 percent, which is the Five Year Average Annual Change Rate (AACR) for Wake County published in the January 2019 SDR.
- The applicant does not assume the patients who utilize the facility and live in another county will continue to dialyze at Southwest Wake County Dialysis.
- In its application for FMC Rock Quarry (Project I.D. # J-11271-16), the applicant projected that eight patients residing in Wake County and dialyzing at Southwest Wake County Dialysis would transfer care to FMC Rock Quarry, and the applicant subtracts the eight patients projected to transfer from the calculations on December 31, 2019 (when FMC Rock Quarry is projected to be certified).
- In its application for FMC West Johnston (Project I.D. # J-11435-17), the applicant projected that the two patients residing in Johnston County and dialyzing at Southwest Wake County Dialysis would transfer care to FMC West Johnston, and the applicant

subtracts the two patients projected to transfer from the calculations on December 31, 2020 (when FMC West Johnston is projected to be certified).

- The project is scheduled for completion on December 31, 2020. OY1 is CY2021. OY2 is CY2022.

In Section C, page 14, the applicant provides the calculations used to arrive at the projected patient census for OY1 and OY2, as summarized in the table below.

<b>Southwest Wake County Dialysis In-Center Projections</b>	
Starting point of calculations is Wake County patients dialyzing in-center at Southwest Wake County Dialysis on December 31, 2018.	111
Wake County patient population is projected forward by one year to December 31, 2019, using the Five Year AACR (4.3%).	$111 \times 1.043 = 115.8$
The applicant subtracts 8 Wake County patients, projected to transfer care to FMC Rock Quarry from the projected patient population.	$115.8 - 8 = 107.8$
The two patients from Johnston County are added. This is the projected census on December 31, 2019.	$107.8 + 2 = 109.8$
Wake County patient population is projected forward by one year to December 31, 2020, using the Five Year AACR (4.3%).	$109.8 \times 1.043 = 112.4$
The two patients from Johnston County are added. This is the projected census on December 31, 2020 (OY1).*	$112.4 + 2 = 114.4$
Wake County patient population is projected forward by one year to December 31, 2021, using the Five Year AACR (4.3%). This is the projected census on December 31, 2021 (OY1).	$114.4 \times 1.043 = 117.2$
Wake County patient population is projected forward by one year to December 31, 2021, using the Five Year AACR (4.3%). This is the projected census on December 31, 2022 (OY2).	$117.2 \times 1.043 = 122.3$

\*Applicant states the Johnston county patients are shown here because they are projected to be dialyzing with the facility throughout the year until their transfer on December 31, 2020.

The applicant projects to serve 117 in-center patients on 30 stations, which is 3.9 patients per station per week ( $117 \text{ patients} / 30 \text{ stations} = 3.9$ ), by the end of OY1 and 122 in-center patients on 30 stations, which is 4.07 patients per station per week ( $122 \text{ patients} / 30 \text{ stations} = 4.07$ ), by the end of OY2. 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). Projected utilization is reasonable and adequately supported for the following reasons:

- The January 2019 SDR states that Southwest Wake County Dialysis’s utilization was 3.73 patients per station per week (a utilization rate of 93.33 percent) as of June 30, 2018.
- The applicant projects future utilization based on historical utilization.
- The applicant uses the Five Year AACR for Wake County as published in the January 2019 SDR to project growth of Wake County residents.
- The applicant reasonably accounts for projected patient utilization by related projects under development.

- The applicant’s projected utilization 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).

**Access**

In Section C, page 15, 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.”*

In Section L, page 49, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

<b>Southwest Wake County Dialysis Projected Payor Mix CY2022</b>	
<b>Payment Source</b>	<b>% of Patients</b>
Self-Pay/Indigent/Charity	2.64%
Medicare	36.79%
Medicaid	14.01%
Commercial Insurance	6.99%
Medicare/Commercial	32.93%
Misc. (including VA)	6.64%
<b>Total</b>	<b>100.00%</b>

The projected payor mix is reasonable and adequately supported.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- 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 to reduce a service, eliminate a service, or relocate 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 no more than two dialysis stations to Southwest Wake County Dialysis for a total of no more than 30 dialysis stations at the facility upon completion of this project and Project I.D. # J-11510-18 (relocate two dialysis stations to FKC Holly Springs).

In Section E, page 21, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo: The applicant states that maintaining the status quo would lead to higher utilization rates and potentially restrict patient admissions. Therefore, this is not an effective alternative.
- Relocate Stations From Another Wake County Facility: The applicant states the patient census at the existing Wake County facilities is growing rapidly and relocating stations from existing facilities is not an effective alternative.

On page 23, the applicant states that its proposal is the most effective alternative because it will have no capital expenditures and is necessary to meet the need for dialysis patients in Wake County.

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 provides 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
- 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 January 2019 SDR, Bio-Medical Applications of North Carolina, Inc. shall develop no more than two additional dialysis station at Southwest Wake County Dialysis for a total of no more than 30 certified stations at Southwest Wake County Dialysis upon completion of this project and Project I.D. # J-11510-18 (relocate two dialysis 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 no more than two dialysis stations to Southwest Wake County Dialysis for a total of no more than 30 dialysis stations at the facility upon completion of this project and Project I.D. # J-11510-18 (relocate two dialysis stations to FKC Holly Springs).

### **Capital and Working Capital Costs**

In Section F.1, page 24, the applicant projects no capital costs for the proposed project. In Sections F.10 and F.11, pages 26 and 27, respectively, the applicant states that there are no projected start-up expenses or initial operating expenses because it is an existing facility that is already operational.

**Financial Feasibility**

The applicant provides pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Form B, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

<b>Projected Revenues and Operating Expenses</b>		
<b>Southwest Wake County Dialysis</b>	<b>Operating Year 1 CY2021</b>	<b>Operating Year 2 CY2022</b>
Total Treatments	16,894	17,635
Total Gross Revenues (Charges)	\$67,373,272	\$70,328,380
Total Net Revenue	\$4,925,760	\$5,141,812
Average Net Revenue per Treatment	\$292	\$292
Total Operating Expenses (Costs)	\$3,970,687	\$4,106,863
Average Operating Expense per Treatment	\$235	\$233
<b>Net Income/Profit</b>	<b>\$955,072</b>	<b>\$1,034,949</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 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

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 no more than two dialysis stations to Southwest Wake County Dialysis for a total of no more than 30 dialysis stations at the facility upon completion of this project and Project I.D. # J-11510-18 (relocate two dialysis 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.

Currently, there are 18 existing and approved dialysis facilities in Wake County, 16 of which are owned by Fresenius Medical Care (FMC). DaVita operates one dialysis facility in Wake County, and has one approved but not yet operational, as shown in the following table:

<b>WAKE COUNTY DIALYSIS FACILITIES</b>				
<b>FACILITY</b>	<b>OWNER</b>	<b>LOCATION</b>	<b># CERTIFIED STATIONS AS OF 6/30/18</b>	<b>UTILIZATION AS OF 6/30/18</b>
FMC New Hope Dialysis	FMC	Raleigh	36	84.72%
BMA of Fuquay Varina Kidney Center	FMC	Fuquay Varina	28	82.14%
BMA of Raleigh Dialysis	FMC	Raleigh	50	92.50%
Cary Kidney Center	FMC	Cary	28	78.57%
FMC Apex	FMC	Apex	20	81.25%
FMC Central Raleigh	FMC	Raleigh	19	69.74%
FMC Eastern Wake	FMC	Rolesville	17	60.29%
FMC Millbrook	FMC	Raleigh	17	79.41%
FMC Northern Wake	FMC	Wake Forest	16	59.38%
Southwest Wake County Dialysis	FMC	Raleigh	30	93.33%
Wake Dialysis Center	FMC	Raleigh	50	99.00%
Zebulon Kidney Center	FMC	Zebulon	30	77.50%
FMC Morrisville	FMC	Morrisville	10*	NA
FMC White Oak	FMC	Garner	12*	NA
FMC Rock Quarry	FMC	Raleigh	10*	NA
FKC Holly Springs	FMC	Holly Springs	10*	NA
Wake Forest Dialysis Center	DaVita	Raleigh	22	101.14%
Oak City Dialysis	DaVita	Raleigh	10*	NA

Source: Table B, January 2019 SDR.

\*Indicates dialysis stations at facilities that were approved but not operational as of June 30, 2018.

As shown in the table above, three of the 12 operational dialysis facilities owned by BMA were being utilized at 90% or higher and nine of the 12 were being utilized at greater than 70.0%.

In Section G, pages 32-33, 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 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, as calculated using the methodology in the January 2019 SDR, for the proposed dialysis station.

- The applicant adequately demonstrates that the proposed dialysis station is needed in addition to the existing or approved dialysis stations.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was 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 H, page 34, the applicant provides information about current and projected staffing for the proposed services. The applicant does not project to change its current staffing levels upon project completion.

Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, which is found in Section R. In Section H, pages 34-35, the applicant describes the methods it uses to recruit or fill new positions and its existing training and continuing education programs. The applicant provides supporting documentation in Exhibits H-1 and H-2. In Section I, page 39, the applicant identifies the current medical director. In Exhibit I-5, the applicant provides a letter from the current medical director expressing his support for the proposed project and indicating his intent to continue serving 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
- 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 37, 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>
In-center dialysis/maintenance	On site
Self-care training (in-center)	Referral to BMA Wake Home Training Program
Home training	
HH	Referral to BMA Wake Home Training Program
PD	Referral to BMA Wake Home Training Program
Accessible follow-up program	Referral to BMA Wake Home Training Program
Psychological counseling	On site
Isolation – hepatitis	On site
Nutritional counseling	On site
Social Work services	On site
Acute dialysis in an acute care setting	WakeMed
Emergency care	Crash cart on site/staff trained; ambulance transport to hospital
Blood bank services	WakeMed
Diagnostic and evaluation services	WakeMed
X-ray services	WakeMed
Laboratory services	Spectra
Pediatric nephrology	UNC Hospitals
Vascular surgery	Carolina Vascular, Wake Surgical, North Raleigh Surgical
Transplantation services	UNC Hospitals
Vocational rehabilitation & counseling	Vocational Rehabilitation Services of Wake County
Transportation	Tri-Star, Johnston Ambulance Services, Wake Coordinated Transport

The applicant provides supporting documentation in Exhibits I-1 through I-4.

In Section I, pages 38-40, the applicant describes its existing relationships with other local health care and social service providers and provides supporting documentation in Exhibits I-4 and I-5.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

## **Conclusion**

The Agency reviewed the:

- Application
- 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 to construct any new space or renovate any existing space. 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 52, the applicant provides the historical payor mix during CY 2018 for its existing services, as shown in the table below.

<b>Southwest Wake County Dialysis Historical Payor Mix CY2018</b>	
<b>Payment Source</b>	<b>% of Patients</b>
Self-Pay/Indigent/Charity	3.12%
Medicare	37.16%
Medicaid	15.47%
Commercial Insurance	6.46%
Medicare/Commercial	33.07%
Misc. (including VA)	4.72%
<b>Total</b>	<b>100.00%</b>

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

<b>Percent of Population</b>						
<b>County</b>	<b>% 65+</b>	<b>% Female</b>	<b>% Racial &amp; Ethnic Minority*</b>	<b>% Persons in Poverty**</b>	<b>% &lt; Age 65 with a Disability</b>	<b>% &lt; Age 65 without Health Insurance**</b>
Wake	11%	51%	40%	11%	6%	10%
Statewide	16%	51%	37%	15%	10%	12%

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

\*Excludes "White alone" who are "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 2016 Annual 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 25-26<sup>1</sup>) 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
- Information which was 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;

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



Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, the applicant states in Section L, pages 50-51, that it has no obligation by any of its facilities to provide uncompensated care or community service under any federal regulations.

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
- 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 49, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

<b>Southwest Wake County Dialysis Projected Payor Mix CY2022</b>	
<b>Payment Source</b>	<b>% of Patients</b>
Self-Pay/Indigent/Charity	2.64%
Medicare	36.79%
Medicaid	14.01%
Commercial Insurance	6.99%
Medicare/Commercial	32.93%
Misc. (including VA)	6.64%
<b>Total</b>	<b>100.00%</b>

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 2.64 percent of services will be provided to self-pay, indigent, and charity care patients; 69.72 percent to patients who will have some or all of their care paid for by Medicare; and 14.01 percent to Medicaid patients.

On page 49, the applicant provides the assumptions and methodology it uses to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

- The projected payor mix is based on the historical payor mix.
- Projected utilization is reasonable and adequately supported. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

### **Conclusion**

The Agency reviewed the:

- Application
- 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 51, the applicant adequately describes the range of means by which patients will have access to the proposed services.

### **Conclusion**

The Agency reviewed the:

- Application
- 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-1.

### **Conclusion**

The Agency reviewed the:

- Application
- 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 no more than two dialysis stations to Southwest Wake County Dialysis for a total of no more than 30 dialysis stations at the facility upon completion of this project and Project I.D. # J-11510-18 (relocate two dialysis 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.

Currently, there are 18 existing and approved dialysis facilities in Wake County, 16 of which are owned by BMA. DaVita operates one dialysis facility in Wake County, and has one approved but not yet operational, as shown in the following table:

<b>WAKE COUNTY DIALYSIS FACILITIES</b>				
FACILITY	OWNER	LOCATION	# CERTIFIED STATIONS AS OF 6/30/18	UTILIZATION AS OF 6/30/18
FMC New Hope Dialysis	FMC	Raleigh	36	84.72%
BMA of Fuquay Varina Kidney Center	FMC	Fuquay Varina	28	82.14%
BMA of Raleigh Dialysis	FMC	Raleigh	50	92.50%
Cary Kidney Center	FMC	Cary	28	78.57%
FMC Apex	FMC	Apex	20	81.25%
FMC Central Raleigh	FMC	Raleigh	19	69.74%
FMC Eastern Wake	FMC	Rolesville	17	60.29%
FMC Millbrook	FMC	Raleigh	17	79.41%
FMC Northern Wake	FMC	Wake Forest	16	59.38%
Southwest Wake County Dialysis	FMC	Raleigh	30	93.33%
Wake Dialysis Center	FMC	Raleigh	50	99.00%
Zebulon Kidney Center	FMC	Zebulon	30	77.50%
FMC Morrisville	FMC	Morrisville	10*	NA
FMC White Oak	FMC	Garner	12*	NA
FMC Rock Quarry	FMC	Raleigh	10*	NA
FKC Holly Springs	FMC	Holly Springs	10*	NA
Wake Forest Dialysis Center	DaVita	Raleigh	22	101.14%
Oak City Dialysis	DaVita	Raleigh	10*	NA

Source: Table B, January 2019 SDR.

\*Indicates dialysis stations at facilities that were approved but not operational as of June 30, 2018.

In Section N, pages 54-55, 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. On page 54, the applicant states:

*“BMA does not expect this proposal to have effect on the competitive climate in Wake County. BMA does not project to serve dialysis patients currently being served by another provider. ... BMA facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients. Every effort is made to (a) ensure that the applicant thoroughly plans for the success of a facility prior to the application, and, (b) that once the project is completed, all staff members work toward the clinical and financial success of the facility. This proposal will certainly not adversely affect quality, but rather, enhance the quality of the ESRD patients’ lives by offering another convenient venue for dialysis care and treatment.”*

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 F and R of the application and any exhibits).
- Quality services will be provided (see Section O of the application and any exhibits).

- Access will be provided to underserved groups (see Section L of the application and any exhibits).

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was 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 Exhibit A-4, 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 a total of 114 dialysis facilities located in North Carolina.

In Section O, page 59, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents related to quality of care resulting in an immediate jeopardy violation that 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 114 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. Therefore, this Rule is not applicable to this review.
  
- (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, page 13, the applicant projects that Southwest Wake County Dialysis will serve 117 patients on 30 stations, or a rate of 3.9 patients per station per week, as of the end of the first operating year following project completion. 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 C, pages 13-14, the applicant provides the assumptions and methodology it uses to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.