

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: February 20, 2020

Findings Date: February 20, 2020

Project Analyst: Mike McKillip

Team Leader: Gloria C. Hale

Project ID #: J-11784-19

Facility: FMC Northern Wake

FID #: 130278

County: Wake

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

Project: Add no more than one dialysis station for a total of no more than 15 stations upon project completion

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 one dialysis station to the existing FMC Northern Wake facility (FMC Northern Wake) for a total of 15 dialysis stations upon project completion.

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 FMC Northern Wake in the July 2019 SDR, page 51, is 3.5 patients per station per week, or 87.5%, based on 49 in-center dialysis patients and 14 certified dialysis stations [49 / 14 = 3.5; 3.5 / 4 = 0.875]. Therefore, FMC Northern Wake is eligible to apply for additional stations based on the facility need methodology.

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

FMC Northern Wake		
OCTOBER 1 REVIEW-JULY 2019 SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/18		87.50%
Certified Stations		14
Pending Stations		0
Total Existing and Pending Stations		14
In-Center Patients as of 12/31/18 (July 2019 SDR) (SDR2)		49
In-Center Patients as of 6/30/18 (January 2019 SDR) (SDR1)		38
Step	Description	Result
	Difference (SDR2 - SDR1)	11
(i)	Multiply the difference by 2 for the projected net in-center change	22
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/18	0.5789
(ii)	Divide the result of Step (i) by 12	0.0482
(iii)	Multiply the result of Step (ii) by 12	0.5789
(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	77.3684
(v)	Divide the result of Step (iv) by 3.2 patients per station	24.1776
	and subtract the number of certified and pending stations to determine the number of stations needed	10.1776

Source: Section B.1, page 10.

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed at FMC Northern Wake is ten 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 one new station; 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, Section N.2(b), page 56; Section O, pages 58-61; 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 12-14, Section C.7, pages 22-23; Section L, pages 50-53; Section N.2(c), page 56; 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 56; 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 one dialysis station to FMC Northern Wake for a total of 15 dialysis stations upon project completion.

The following table, from page 7 of the application, shows the current and projected number of dialysis stations at FMC Northern Wake.

FMC Northern Wake

# of Stations	Description	Project ID #
14	Total # of existing certified stations as reported in the SDR in effect on the day the review will begin	
1	# of stations to be added as part of this project	J-11784-19
	# of stations to be deleted as part of this project	
	# of stations previously approved to be added but not yet certified	
	# of stations previously approved to be deleted but not yet certified	
	# of stations proposed to be added in an application still under review	
	# of stations proposed to be deleted in an application still under review	
15	Total # of stations upon completion of all facility projects	

As outlined in the table above, in this application, the applicant proposes to add one dialysis station for a total of 15 stations upon the project completion.

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 (IC), home hemodialysis (HH), and peritoneal dialysis (PD) patients at FMC Northern Wake for the last full operating year (CY2018), as summarized in the table below.

FMC Northern Wake Patient Origin - CY2018

COUNTY	# IC PATIENTS	% IC Total	# HH Patients	% HH Total	# PD Patients	% PD Total
Wake	45	92.0%	2	100.0%	11	79.0%
Durham	0	0.0%	0	0.0%	3	21.0%
Franklin	4	8.0%	0	0.0%	0	0.0%
Total	49	100.0%	2	100.0%	14	100.0%

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.3, page 17.

Projected Patient Origin FMC Northern Wake - OY2 CY2022

COUNTY	# IC PATIENTS	% IC Total	# HH Patients	% HH Total	# PD Patients	% PD Total
Wake	47.5	90.0%	2.3	100.0%	14.7	88.0%
Durham	1.0	2.0%	0.0	0.0%	0.0	0.0%
Franklin	4.0	8.0%	0.0	0.0%	2.0	12.0%
Total	52.5	100.0%	2.3	100.0%	16.7	100.0%

Totals may not sum due to rounding

In Section C, pages 18-23, the applicant provides the assumptions and methodology it used to project IC, HH, and PD patient origin. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section Q, pages 70-73, 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 70 that shows the facility census as of December 31, 2018 and June 30, 2019, as summarized below.

**FMC Northern Wake
 In-Center Patients**

COUNTY	12/31/2018	6/30/2019
Wake	45	42
Durham	0	1
Franklin	4	4
Mecklenburg	0	1
Total	49	48

- The applicant states that it assumes the patients from Wake County dialyzing at FMC Northern Wake 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 assumes the June 30, 2019 patients from Franklin County and Durham County will continue to dialyze at FMC Northern Wake but does not assume any growth in patients from these counties. The applicant assumes no patients from Mecklenburg County will continue to dialyze at the facility.
- 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.

In-Center Projected Utilization

In Section Q, page 71, the applicant provided the methodology used to project in-center utilization, as illustrated in the following table,

The applicant begins with the Wake County in-center patients at FMC Northern Wake as of June 30, 2019.	42
The applicant projects the Wake County patients forward six months to December 31, 2019 using one-half of the Wake County Five Year AACR of 3.6 percent, which is 1.8 percent.	$42 \times 1.018 = 42.8$
The applicant projects the Wake County in-center patients forward one year to December 31, 2020 using the Wake County Five Year AACR.	$42.8 \times 1.036 = 44.3$
The applicant adds five patients from Franklin and Durham counties who dialyze at FMC Northern Wake.	$44.3 + 5 = 49.3$
The applicant projects the Wake County in-center patients forward one year to December 31, 2021 using the Wake County Five Year AACR.	$44.3 \times 1.036 = 45.9$
The applicant adds five patients from Franklin and Durham counties who dialyze at FMC Northern Wake. This is the projected ending census for Operating Year 1 .	$45.9 + 5 = 50.9$
The applicant projects the Wake County in-center patients forward one year to December 31, 2022 using the Wake County Five Year AACR.	$45.9 \times 1.036 = 47.5$
The applicant adds five patients from Franklin and Durham counties who dialyze at FMC Northern Wake. This is the projected ending census for Operating Year 2 .	$47.5 + 5 = 52.5$

The applicant projects to serve 51 in-center patients in OY1 and 53 in-center patients in OY2. Thus, the applicant projects that FMC Northern Wake will have a utilization rate of 85% or 3.4 patients per station per week ($51 \text{ patients} / 15 \text{ stations} = 3.4 / 4 = 0.85$ or 85%) in OY1. The projected utilization of 3.4 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:

- The applicant begins the projections with the existing Wake County FMC Northern Wake patient census as of June 30, 2019.
- The applicant projects the Wake County patient census at FMC Northern Wake will increase by the Wake County Five Year AACR of 3.6 percent, as reported in the July 2019 SDR.
- The utilization rate by the end of OY1 is above the minimum standard of 3.2 patients per station per week.

Home Therapy Projected Utilization

In Section Q, pages 72-73, the applicant makes the following assumptions in the projection of home therapies:

- The applicant states that it projects patients forward from the June 30, 2019 census data. The applicant provides a table on page 73 that shows the facility census as of December 31, 2018 and June 30, 2019, as summarized below.

**FMC Northern Wake
Home Therapy Patients**

COUNTY	DECEMBER 31, 2018		JUNE 30, 2019	
	HH	PD	HH	PD
Wake	2	11	2	13
Franklin	0	3	0	2
Total	2	14	2	15

As shown in the table above, the applicant reports two HH patients and 15 PD patients were served at FMC Northern Wake as of June 30, 2019.

- The applicant states that it assumes the patients from Wake County dialyzing at FMC Northern Wake on June 30, 2019 will continue to dialyze there and will increase at a rate equal to the 3.6% Wake County Five Year AACR published in the July 2019 SDR.
- The applicant assumes the HH and PD patients from outside of Wake County will continue to dialyze at FMC Northern Wake but does not assume any growth in patients from these counties.
- 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.

In Section Q, page 73, the applicant provided the methodology used to project home therapy utilization, as illustrated in the following table.

FMC Northern Wake Home Therapy Programs	HH	PD
The applicant begins with the Wake County home therapy patients as of June 30, 2019.	2	13
The applicant projects the Wake County patients forward six months to December 31, 2019 using one-half of the Wake County Five Year AACR of 3.6 percent, which is 1.8 percent.	$2 \times 1.018 = 2.04$	$13 \times 1.018 = 13.23$
The applicant projects the Wake County patients forward one year to December 31, 2020 using the Wake County Five Year AACR.	$2.04 \times 1.036 = 2.1$	$13.23 \times 1.036 = 13.7$
The applicant adds home therapy patients from Franklin County who dialyze at FMC Northern Wake.	$2.1 + 0 = 2.1$	$13.7 + 2 = 15.7$
The applicant projects the Wake County patients forward one year to December 31, 2021 using the Wake County Five Year AACR.	$2.1 \times 1.036 = 2.19$	$13.7 \times 1.036 = 14.2$
The applicant adds home therapy patients from Franklin County who dialyze at FMC Northern Wake. This is the projected ending census for Operating Year 1 .	$2.19 + 0 = 2.19$	$14.2 + 2 = 16.2$
The applicant projects the Wake County in-center patients forward one year to December 31, 2022 using the Wake County Five Year AACR.	$2.19 \times 1.036 = 2.26$	$14.2 \times 1.036 = 14.7$
The applicant adds home therapy patients from Franklin County who dialyze at FMC Northern Wake. This is the projected ending census for Operating Year 2 .	$2.26 + 0 = 2.26$	$14.7 + 2 = 16.7$

At the end of OY1 (CY2021) FMC Northern Wake is projected to serve two HH patients and 16 PD patients; and at the end of OY2 (CY2022) the facility is projected to serve two HH patients and 17 PD patients.

Projected utilization of the home training program is reasonable and adequately supported for the following reasons:

- The applicant projects growth in the Wake County home training patient population using the Wake County Five Year AACR of 3.6%, as published in the July 2019 SDR.
- The applicant does not project growth for patients residing outside of Wake County.

Access

In Section C.7, pages 22-23, 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 52, 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.

**FMC Northern Wake
 Projected Payor Mix CY 2022**

Payment Source	In-Center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	1.11	2.12%	0.00	0.00%	0.00	0.00%
Commercial Insurance*	5.23	9.95%	2.15	94.79%	4.23	25.32%
Medicare*	31.86	60.63%	0.00	0.00%	10.69	63.96%
Medicaid*	2.71	5.17%	0.00	0.00%	0.00	0.00%
Medicare/Commercial	11.38	21.66%	0.12	5.21%	1.79	10.72%
Miscellaneous (Incl. VA)	0.25	0.48%	0.00	0.00%	0.00	0.00%
Total	52.54	100.00%	2.26	100.00%	16.72	100.00%

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
- 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 one dialysis station at FMC Northern Wake for a total of 15 dialysis stations upon project completion. In Section E, pages 28-29, 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 FMC Northern Wake area. The applicant states that failure to add the station will result in higher utilization rates at the facility and fewer opportunities for patient admission.
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 leave the facilities short of stations at that location. 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 the stated facilities would be inappropriate under the existing circumstances listed with each facility, as discussed on pages 28-29.

On page 30, the applicant states that after considering the above alternatives, it elected to add one station because this proposal is the most cost-effective approach to providing the necessary services for the patient population projected to be served at FMC Northern Wake.

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
- 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 one additional dialysis station at FMC Northern Wake for a total of no more than 15 certified dialysis stations upon completion of the project, 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 one dialysis station to FMC Northern Wake for a total of 15 dialysis stations upon project completion.

Capital and Working Capital Costs

In Form F.1(a), page 76, the applicant projects the total capital cost of the project as shown in the table below:

ITEM	AMOUNT
Construction Costs	\$0
Equipment and Furniture	\$3,750
Miscellaneous Costs	\$0
Total	\$3,750

In Section F.3, pages 32-33, the applicant states there will be no start-up expenses or initial operating expenses incurred for this project because FMC Northern Wake is an operational facility.

Availability of Funds

In Section F.2, page 31, the applicant states that the capital cost will be funded as shown in the table below.

TYPE	SOURCE
Loans	0
Accumulated Reserves or OE*	\$3,750
Other (Specify)	0
Total	\$3,750

*OE = Owner's Equity

Exhibit F-1 contains a letter dated September 16, 2019 from the Senior Vice President and Treasurer of Fresenius Medical Care Holdings, Inc. (FMCH), parent company of FMC Northern Wake, authorizing and committing cash reserves in the amount of \$3,750 for the capital costs of the project. The letter states that FMCH currently has \$1.8 billion in cash and cash equivalents and \$20 billion in total assets.

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, page 79, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as summarized in the table below.

FMC Northern Wake Projected Revenue and Operating Expenses

	OY 1 CY2021	OY 2 CY2022
Total Treatments (IC, HH, and PD)	10,093	10,419
Total Gross Revenue (charges)	\$63,496,049	\$65,547,278
Total Net Revenue	\$3,799,725	\$3,922,931
Average Net Revenue per Treatment	\$376	\$377
Total Operating Expenses (costs)	\$2,728,189	\$2,804,221
Average Operating Expense per Treatment	\$270	\$269
Net Income / Profit	\$1,071,536	\$1,118,710

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
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
 - The applicant adequately demonstrates the availability of 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 one dialysis station to FMC Northern Wake for a total of 15 dialysis stations upon project completion.

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.1, pages 36-37, the applicant provides the Wake County BMA facility utilization for the periods ended December 31, 2018 and June 30, 2019. In Section G.2, page 38, 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 one dialysis station to FMC Northern 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 FMC Northern Wake, as calculated using the methodology in the July 2019 SDR, for the proposed one additional dialysis station.
- The applicant adequately demonstrates that the one 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 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 87, the applicant provides a table showing current and projected staffing in full time equivalent (FTE) positions for FMC Northern Wake, 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	2.00	2.00	2.00
Home Training RN	1.00	1.00	1.00
Patient Care Technician	4.00	4.00	4.00
Dietician	0.75	0.75	0.75
Social Worker	0.75	0.75	0.75
Equipment Technician	0.50	0.50	0.50
Administration	1.00	1.00	1.00
FMC Director Operations	0.15	0.15	0.15
In-Service	0.15	0.15	0.15
Chief Technician	0.15	0.15	0.15
Total	11.45	11.45	11.45

Source: Section Q Form H

The assumptions and methodology used to project 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 40, 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 41, the applicant identifies the current medical director for the facility. In Exhibit H-4, the applicant provides a letter from the medical director 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
- 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 43, 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:

ANCILLARY AND SUPPORT SERVICES	
SERVICES	PROVIDER
Self-care training	BMA on site
Home training HH PD Accessible follow-up program	BMA on site
Psychological counseling	Referral to Monarch Counseling Services or Wake County DHHS
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 WakeMed, Duke Raleigh Hospital or Rex Hospital
Emergency care	BMA staff until ambulance transport to hospital
Blood bank services	Referral to Rex Hospital
Diagnostic and evaluation services	Referral to Wake Radiology, WakeMed or Rex Hospital
X-ray services	Referral to Wake Radiology, WakeMed or Rex Hospital
Laboratory services	BMA on site
Pediatric nephrology	Referral to UNC Healthcare
Vascular surgery	Referral to Rex Hospital; Raleigh Access Center; WakeMed Vascular
Transplantation services	Referral to UNC Healthcare
Vocational rehabilitation & counseling	Referral to NC DHHS Vocational Rehabilitation
Transportation	Go Raleigh or Go Wake transportation services

Source: Table in Section I, page 43

In Section I, page 43, 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
- 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 with this project. 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 51, the applicant provides the historical payor mix for FMC Northern Wake patients during CY2018 for its existing services, as shown in the table below.

**FMC Northern Wake
 Historical Payor Mix CY2018**

Payment Source	In-Center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	1.04	2.12%	0.00	0.00%	0.00	0.00%
Commercial Insurance*	4.87	9.95%	1.90	94.79%	3.54	25.32%
Medicare*	29.71	60.63%	0.00	0.00%	8.95	63.96%
Medicaid*	2.53	5.17%	0.00	0.00%	0.00	0.00%
Medicare/Commercial	10.61	21.66%	0.10	5.21%	1.50	10.72%
Miscellaneous (Incl. VA)	0.24	0.24%	0.00	0.00%	0.00	0.00%
Total	49.00	100.00%	2.00	100.00%	14.00	100.00%

Totals may not sum due to rounding

*Including any managed care plans

In Section L.1(a), page 51, the applicant provides comparison of the demographical information on FMC Northern Wake 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	35.8%	51.3%
Male	64.2%	48.7%
Unknown		
64 and Younger	58.2%	88.4%
65 and Older	41.8%	11.6%
American Indian	0.0%	0.8%
Asian	9.0%	7.5%
Black or African-American	56.7%	21.0%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	32.8%	59.8%
Other Race	0.0%	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
- 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, pages 51-52, 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 52, 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 52, 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.

**FMC Northern Wake
 Projected Payor Mix CY 2022**

Payment Source	In-Center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	1.11	2.12%	0.00	0.00%	0.00	0.00%
Commercial Insurance*	5.23	9.95%	2.15	94.79%	4.23	25.32%
Medicare*	31.86	60.63%	0.00	0.00%	10.69	63.96%
Medicaid*	2.71	5.17%	0.00	0.00%	0.00	0.00%
Medicare/Commercial	11.38	21.66%	0.12	5.21%	1.79	10.72%
Miscellaneous (Incl. VA)	0.25	0.48%	0.00	0.00%	0.00	0.00%
Total	52.54	100.00%	2.26	100.00%	16.72	100.00%

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 2.12% of in-center dialysis services will be provided to self-pay patients, 82.29% to Medicare patients (includes Medicare and Medicare/Commercial), and 5.17% to Medicaid patients.

On page 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 projected payor mix is reasonable and adequately supported because the projected payor mix is based on the historical payor mix of FMC Northern Wake.

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 53, 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 54, 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
- 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 one dialysis station to FMC Northern Wake for a total of 15 dialysis stations upon completion of the project.

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 one dialysis station to the existing facility in Wake County pursuant to the facility need determination methodology.

In Section N, pages 55-57, 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 FMC Northern 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, N and Q of the application and any exhibits).
- Quality services will be provided (see Sections B, N and O of the application and any exhibits).
- Access will be provided to underserved groups (see Sections B, N and L of the application and any exhibits).

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.

- (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.2, page 61, 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- FMC Northern Wake 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 71, the applicant projects that FMC Northern Wake will serve 51 in-center patients on 15 stations, or a rate of 3.4 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.

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

- C- In Section Q, pages 70-73, the applicant provides the assumptions and methodology it used to project utilization of the facility.