

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 25, 2020

Findings Date: June 25, 2020

Project Analyst: Mike McKillip

Team Leader: Fatimah Wilson

Project ID #: J-11879-20

Facility: FMC Northern Wake

FID #: 130278

County: Wake

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

Project: Add no more than three dialysis stations pursuant to the facility need determination for a total of no more than 18 stations which is a change of scope for Project I.D. # J-11784-19 (add one dialysis station)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Agency shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C

Bio-Medical Applications of North Carolina, Inc. (hereinafter referred to as “the applicant” or BMA) proposes to add no more than three dialysis stations to the existing FMC Northern Wake facility pursuant to the facility need determination for a total of no more than 18 stations which is a change of scope for Project I.D. # J-11784-19 (add one dialysis station).

Need Determination (Condition 2)

Chapter 9 of the 2020 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 Table 9D, page 170, the county need methodology shows there is not a county need determination for additional dialysis stations in Wake County.

However, the applicant is eligible to apply for additional dialysis stations in an existing facility pursuant to Condition 2 of the facility need methodology in the 2020 SMFP, if the utilization rate for the dialysis center as reported in the 2020 SMFP is at least 75 percent or 3.0 patients per station per week, as stated in Condition 2.a. The utilization rate reported for FMC Northern Wake on page 164 of the 2020 SMFP is 87.50 percent or 3.5 patients per station per week, based on 49 in-center dialysis patients and 14 certified dialysis stations (49 patients / 14 stations = 3.5; $3.5 / 4 = 87.50\%$).

As shown in Table 9E on page 173 of the 2020 SMFP, based on the facility need methodology for dialysis stations, the potential number of stations needed at FMC Northern Wake is up to five additional stations; thus, the applicant is eligible to apply to add up to five stations during the 2020 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than three new stations to FMC Northern Wake, which is consistent with the 2020 SMFP calculated facility need determination for up to five dialysis stations; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

Policies

There is one policy in the 2020 SMFP which is applicable to this review. Policy GEN-3: Basic Principles, on pages 30-31 of the 2020 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.5 (a) and (d), pages 14-17, Section N.2(b), page 54; Section O, pages 56-59; 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.5 (b) and (d), pages 15-17, Section C.7, pages 23-24; Section L, pages 47-51; Section N.2(c), page 54; 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.5 (c) and (d), pages 16-17; Section N.2(a), page 54; 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 three dialysis stations to the existing FMC Northern Wake facility pursuant to the facility need determination for a total of no more than

18 stations. Effective March 24, 2020, in Project I.D. # J-11784-19, the applicant was approved to add one dialysis station to FMC Northern Wake. That project was completed on April 6, 2020. Because the applicant proposes to add three stations to FMC Northern Wake facility within 12 months of development of Project I.D. J-11784-20, this application is considered a change of scope to Project I.D. J-11784-20.

The following table, summarized 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	
3	# of stations to be added as part of this project	J-11879-20
	# of stations to be deleted as part of this project	
1	# of stations previously approved to be added but not yet certified	J-11784-19
	# 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	
18	Total # of stations upon completion of all facility projects	

As outlined in the table above, in this application, the applicant proposes to add three dialysis stations for a total of 18 stations upon the project completion.

Patient Origin

On page 113, the 2020 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service area: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancey counties.*” 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 19, 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 (CY2019), as summarized in the table below.

FMC Northern Wake Patient Origin - CY2019

COUNTY	# IC PATIENTS	% IC Total	# HH Patients	% HH Total	# PD Patients	% PD Total
Wake	43	89.6%	3	75.0%	17	94.4%
Franklin	4	8.3%	1	25.0%	1	5.6%
Mecklenburg	1	2.1%	0	0.0%	0	0.0%
Total	48	100.0%	4	100.0%	18	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 19.

Projected Patient Origin FMC Northern Wake - OY2 CY2022

COUNTY	# IC PATIENTS	% IC Total	# HH Patients	% HH Total	# PD Patients	% PD Total
Wake	49.75	92.6%	3.32	76.8%	18.79	94.9%
Franklin	4.00	7.4%	1.00	23.2%	1.00	5.1%
Total	53.70	100.0%	4.30	100.0%	19.80	100.0%

Totals may not sum due to rounding

In Section C, pages 20-22, the applicant provides the assumptions and methodology it used to project IC, HH, and PD patient origin. The applicant states that the in-center and home therapies patient origin is based upon the facility census as of February 29, 2020. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section Q, pages 69-71, 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 February 29, 2020 census data. The applicant states that it assumes the patients from Wake County dialyzing at FMC Northern Wake on February 29, 2020 will continue to dialyze there and will increase at a rate equal to the Wake County Five Year Average Annual Change Rate (AACR) of 3.6% as published in the 2020 SMFP.
- The applicant assumes the patients from Franklin County will continue to dialyze at FMC Northern Wake but does not assume any growth in patients from Franklin County.
- The project is scheduled for completion on 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 70, 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 as of February 29, 2020.	45
The applicant projects the Wake County in-center patients forward ten months to December 31, 2020 using the Wake County AACR prorated for ten months.	$45 \times 1.030 = 46.4$
The applicant adds four Franklin County patients. This is the starting in-center census for the proposed project.	$46.4 + 4 = 50.4$
The applicant projects the Wake County in-center patients forward one year to December 31, 2021 using the Wake County AACR.	$46.4 \times 1.036 = 48.02$
The applicant adds four Franklin County patients. This is the projected ending census for Operating Year 1 .	$48.02 + 4 = 52.02$
The applicant projects the Wake County in-center patients forward one year to December 31, 2022 using the Wake County AACR.	$48.02 \times 1.06 = 49.75$
The applicant adds four Franklin County patients. This is the projected ending census for Operating Year 2 .	$49.75 + 4 = 53.75$

The applicant projects to serve 52 in-center patients in OY1 and 54 in-center patients in OY2. Thus, the applicant projects that FMC Northern Wake will have a utilization rate of 72.2% or 2.89 patients per station per week ($52 \text{ patients} / 18 \text{ stations} = 2.89 / 4 = 0.722$ or 72.2%) in OY1. The projected utilization of 2.89 patients per station per week at the end of OY1 exceeds the minimum standard of 2.8 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 February 29, 2020.
- 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 2020 SMFP.
- The utilization rate by the end of OY1 is above the minimum standard of 2.8 patients per station per week.

Home Therapy Projected Utilization

In Section Q, pages 70-71, the applicant makes the following assumptions in the projection of home therapies:

- The applicant states that it projects patients forward from the February 29, 2020 census data.
- The applicant states that it assumes the patients from Wake County dialyzing at FMC Northern Wake on February 29, 2020 will continue to dialyze there and will increase at a rate equal to the Wake County Five Year AACR of 3.6%, as reported in the 2020 SMFP.

- The applicant assumes the HH and PD patients from Franklin County will continue to dialyze at FMC Northern Wake but does not assume any growth in patients from that county.
- 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 71, 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 February 29, 2020.	3	17
The applicant projects the Wake County patients forward to December 31, 2020 using the Wake County AACR of 3.6 percent, pro-rated for ten months.	$3 \times 1.030 = 3.09$	$17 \times 1.030 = 17.51$
The applicant adds home therapy patients from Franklin County who dialyze at FMC Northern Wake.	$3.09 + 1 = 4.09$	$17.51 + 1 = 18.51$
The applicant projects the Wake County patients forward to December 31, 2021 using the Wake County AACR of 3.6 percent.	$3.09 \times 1.036 = 3.2$	$17.51 \times 1.036 = 18.14$
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 .	$3.2 + 1 = 4.2$	$18.14 + 1 = 19.14$
The applicant projects the Wake County in-center patients forward one year to December 31, 2022 using the Wake County AACR.	$3.2 \times 1.036 = 3.32$	$18.14 \times 1.036 = 18.79$
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 .	$3.32 + 1 = 4.32$	$18.79 + 1 = 19.79$

At the end of OY1 (CY2021) FMC Northern Wake is projected to serve 4 HH patients and 19 PD patients; and at the end of OY2 (CY2022) the facility is projected to serve 4 HH patients and 20 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 reported in the 2020 SMFP.
- The applicant does not project growth for patients residing outside of Wake County.

Access

In Section C.7, pages 23-24, 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.3, page 49, 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 CY2022**

Payment Source	In-Center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	1.15	2.15%	0.02	0.42%	0.23	1.17%
Insurance*	3.49	6.50%	0.84	19.36%	4.69	23.71%
Medicare*	33.36	62.06%	2.88	66.82%	10.89	54.99%
Medicaid*	2.21	4.11%	0.10	2.37%	0.90	4.53%
Medicare/Commercial	10.15	18.89%	0.31	7.15%	2.39	12.06%
Miscellaneous (Incl. VA)	3.38	6.29%	0.17	3.88%	0.70	3.54%
Total	53.75	100.00%	4.32	100.00%	19.79	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 no more than three dialysis stations to the existing FMC Northern Wake facility pursuant to the facility need determination for a total of no more than 18 stations which is a change of scope for Project I.D. # J-11784-19 (add one dialysis station).

In Section E, page 30, 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 is not an effective alternative because of the growth rate at the facility.
- *Applying for fewer than three stations* – The applicant states that this alternative is less effective due the growth rate at the facility.
- *Applying for more than three stations* – The applicant states that this alternative was less effective because the existing FMC Northern Wake facility does not have adequate capacity to accommodate more than the proposed stations.

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 2020 State Medical Facilities Plan, Bio-Medical Applications of North Carolina, Inc. shall develop no more than three additional dialysis stations at FMC Northern Wake for a total of no more than 18 certified dialysis stations upon completion of this project and Project I.D. # J-11784-19 (add one dialysis station), 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 three dialysis stations to the existing FMC Northern Wake facility pursuant to the facility need determination for a total of no more than 18 stations which is a change of scope for Project I.D. # J-11784-19 (add one dialysis station).

Capital and Working Capital Costs

In Form F.1(a), page 75, the applicant projects the total capital cost of the project as shown in the table below:

ITEM	AMOUNT
Construction Costs	\$0
Equipment and Furniture	\$11,250
Miscellaneous Costs	\$0
Total	\$11,250

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	BIO-MEDICAL APPLICATIONS OF NORTH CAROLINA, INC.
Loans	\$0
Accumulated Reserves or OE*	\$11,250
Other (Specify)	\$0
Total	\$11,250

*OE = Owner's Equity

Exhibit F-1 contains a letter dated March 16, 2020 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 \$11,250 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 76, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as summarized in the table below.

	OY 1 CY2021	OY 2 CY2022
Total Treatments (IC, HH, and PD)	10,975	11,338
Total Gross Revenue (charges)	\$69,043,441	\$71,327,894
Total Net Revenue	\$3,764,224	\$3,888,874
Average Net Revenue per Treatment	\$343	\$343
Total Operating Expenses (costs)	\$3,114,463	\$3,194,338
Average Operating Expense per Treatment	\$284	\$282
Net Income / Profit	\$649,761	\$694,535

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 availability of sufficient funds for the capital needs of the proposal.
 - 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 no more than three dialysis stations to the existing FMC Northern Wake facility pursuant to the facility need determination for a total of no more than 18 stations which is a change of scope for Project I.D. # J-11784-19 (add one dialysis station).

On page 113, the 2020 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancey counties.*” Thus, the service area for this application is Wake County. Facilities may serve residents of counties not included in their service area.

The applicant, BMA, currently operates 14 dialysis centers and 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 operates two dialysis centers in Wake County; Wake Forest Dialysis Center and Oak City Dialysis. However, Oak City Dialysis did not become operational until June 2019. See the following table that shows the existing and approved dialysis facilities in Wake County, from Table 9B, pages 163-164 of the 2020 SMFP:

Wake County Dialysis Facilities

Dialysis Facility	Certified Stations 12/31/18	In-Center Patients 12/31/18	Utilization Percent 12/31/18
BMA of Fuquay-Varina Kidney Center (BMA)	28	95	84.82%
BMA of Raleigh Dialysis (BMA)	50	181	90.50%
Cary Kidney Center (BMA)	24	86	89.58%
FMC Eastern Wake (BMA)	17	44	64.71%
FMC Morrisville (BMA)	10	18	45.00%
FMC New Hope Dialysis (BMA)	36	124	86.11%
FMC Northern Wake (BMA)	14	49	87.50%
Wake Dialysis Clinic (BMA)	50	197	98.50%
FKC Holly Springs (BMA)	0	0	NA
FMC Apex (BMA)	20	66	82.50%
FMC Central Raleigh (BMA)	19	51	67.11%
FMC Millbrook (BMA)	17	52	76.47%
FMC Rock Quarry (BMA)	0	0	NA
FMC White Oak (BMA)	12	30	62.50%
Oak City Dialysis (DaVita)	0	0	NA
Southwest Wake County Dialysis (BMA)	30	114	95.00%
Wake Forest Dialysis Center (DaVita)	22	87	98.86%
Zebulon Kidney Center (BMA)	30	104	86.67%

Source: 2020 SMFP, Table 9B.

In Section G.2, page 37, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Wake County. The applicant states:

“This is a proposal to add three dialysis stations to an existing dialysis facility. The stations are needed by the patient population projected to be served by the facility. The projections of future patient populations to be served begins with the current patient population of the facility and an increase of that population at a rate of 3.6%. The applicant has not projected to serve patients currently served in another facility, or served by another provider. The stations are needed at FMC Northern Wake to support the growing patient census at the facility.”

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 2020 SMFP, for the proposed three additional dialysis stations.
- The applicant adequately demonstrates that the three proposed dialysis stations are 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 84, 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 3/16/20	FTE POSITIONS OY1	FTE POSITIONS OY2
FMC Clinic Manager	1.00	1.00	1.00
RN	2.50	3.00	3.00
Home Training RN	2.00	2.00	2.00
Patient Care Technician	5.00	6.00	6.00
Dietician	1.00	1.05	1.05
Social Worker	1.00	1.05	1.05
Equipment Technician	1.00	1.00	1.00
Administration	0.00	1.00	1.00
FMC Director Operations	0.15	0.15	0.15
In-Service	0.20	0.20	0.20
Chief Technician	0.20	0.20	0.20
Total	14.05	15.65	15.65

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 38, 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 39, 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 40, 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; Triangle Vascular; Raleigh Access Center; WakeMed Vascular
Transplantation services	Referral to UNC Healthcare
Vocational rehabilitation & counseling	Referral to NC DHHS Vocational Rehabilitation
Transportation	Go Raleigh or local taxi service

Source: Table in Section I, page 40

In Section I, pages 40-41, the applicant describes its existing and proposed relationships with other local health care and social service providers.

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 48, the applicant provides the historical payor mix for FMC Northern Wake patients during CY2019 for its existing services, as shown in the table below.

**FMC Northern Wake
 Historical Payor Mix (CY2019)**

Payment Source	In-Center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	1.03	2.15%	0.00	0.00%	0.00	0.00%
Insurance*	3.12	6.50%	3.28	81.95%	4.16	23.11%
Medicare*	29.79	62.06%	0.34	8.49%	12.34	68.55%
Medicaid*	1.97	4.11%	0.00	0.00%	0.00	0.00%
Medicare/Commercial	9.07	18.89%	0.00	0.00%	1.50	8.34%
Miscellaneous (Incl. VA)	3.02	6.29%	0.38	9.55%	0.00	0.00%
Total	48	100.00%	4	100.00%	18	100.00%

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

In Section L.1(a), page 47, the applicant provides comparison of the demographical information on FMC Northern Wake patients and the service area patients during CY2019, as summarized below.

	Percentage of Total Patients Served during the Last Full OY	Percentage of the Population of the Service Area*
Female	38.6%	51.3%
Male	61.4%	48.7%
Unknown		
64 and Younger	54.3%	88.4%
65 and Older	45.7%	11.6%
American Indian	0.0%	0.8%
Asian	2.9%	7.5%
Black or African-American	60.0%	21.0%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	32.9%	59.8%
Other Race	2.9%	10.8%
Declined / Unavailable	1.4%	

* 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 48-49, 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 49, 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.3, page 49, 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 CY2022**

Payment Source	In-Center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	1.15	2.15%	0.02	0.42%	0.23	1.17%
Insurance*	3.49	6.50%	0.84	19.36%	4.69	23.71%
Medicare*	33.36	62.06%	2.88	66.82%	10.89	54.99%
Medicaid*	2.21	4.11%	0.10	2.37%	0.90	4.53%
Medicare/Commercial	10.15	18.89%	0.31	7.15%	2.39	12.06%
Miscellaneous (Incl. VA)	3.38	6.29%	0.17	3.88%	0.70	3.54%
Total	53.75	100.00%	4.32	100.00%	19.79	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 2.15% of in-center dialysis services will be provided to self-pay patients, 80.95% to Medicare patients (includes Medicare and Medicare/Commercial), and 4.11% to Medicaid patients.

On page 48, the applicant provides the assumptions and methodology it uses to project payor mix during the second full year of operation following completion of the project, stating the payor mix is based upon recent facility history of actual treatment volumes. The applicant explains that Fresenius reports payor source of treatments, not whole patients as requested in the table, which the applicant states provides a clear indication of the source of revenue.

The projected payor mix is reasonable and adequately supported because the projected payor mix is based on the historical payor mix of 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.5, page 50, 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 52, 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 no more than three dialysis stations to the existing FMC Northern Wake facility pursuant to the facility need determination for a total of no more than 18 stations which is a change of scope for Project I.D. # J-11784-19 (add one dialysis station).

On page 113, the 2020 SMFP defines the service area for dialysis stations as *“the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancey counties.”* Thus, the service area for this application is Wake County. Facilities may serve residents of counties not included in their service area.

The applicant, BMA, currently operates 14 dialysis centers and 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 operates two dialysis centers in Wake County; Wake Forest Dialysis Center and Oak City Dialysis. However, Oak City Dialysis did not become operational until June 2019. See the following table that shows the existing and approved dialysis facilities in Wake County, from Table 9B, pages 163-164 of the 2020 SMFP:

Wake County Dialysis Facilities

Dialysis Facility	Certified Stations 12/31/18	In-Center Patients 12/31/18	Utilization Percent 12/31/18
BMA of Fuquay-Varina Kidney Center (BMA)	28	95	84.82%
BMA of Raleigh Dialysis (BMA)	50	181	90.50%
Cary Kidney Center (BMA)	24	86	89.58%
FMC Eastern Wake (BMA)	17	44	64.71%
FMC Morrisville (BMA)	10	18	45.00%
FMC New Hope Dialysis (BMA)	36	124	86.11%
FMC Northern Wake (BMA)	14	49	87.50%
Wake Dialysis Clinic (BMA)	50	197	98.50%
FKC Holly Springs (BMA)	0	0	NA
FMC Apex (BMA)	20	66	82.50%
FMC Central Raleigh (BMA)	19	51	67.11%
FMC Millbrook (BMA)	17	52	76.47%
FMC Rock Quarry (BMA)	0	0	NA
FMC White Oak (BMA)	12	30	62.50%
Oak City Dialysis (DaVita)	0	0	NA
Southwest Wake County Dialysis (BMA)	30	114	95.00%
Wake Forest Dialysis Center (DaVita)	22	87	98.86%
Zebulon Kidney Center (BMA)	30	104	86.67%

Source: 2020 SMFP, Table 9B.

Regarding the expected effects of the proposal on competition in the service area, in Section N.1, page 53, 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 with the current patient population and projects growth of that population consistent with the Wake County Five Year Average Annual Change Rate published in the 2020 SMFP.”

Regarding the impact of the proposal on cost effectiveness, in Section N.2, page 54, the applicant states:

“This is a proposal to add three stations to the FMC Northern Wake facility. The applicant is serving a significant number of dialysis patients residing in the area of the facility. Approval of this application will allow the FMC Northern Wake facility to continue serving patients who reside in the area. Consequently, these patients will have a shorter commute to and from dialysis treatment. This is an immediate and significantly positive impact to the patients of the area.”

Regarding the impact of the proposal on quality, in Section N.2, page 54, the applicant states:

“Quality of care is always in the forefront at Fresenius related facilities. Quality care is not negotiable. Fresenius Medical Care, parent organization for this facility, expects every facility to provide high quality care to every patient at every treatment.”

Regarding the impact of the proposal on access by medically underserved groups, in Section N.2, page 54, the applicant states:

“All Fresenius related facilities in North Carolina have a history of providing dialysis services to the underserved populations of North Carolina. The Form A identifies all Fresenius related operational and/or CON approved facilities across North Carolina. Each of those facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons. ... 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. Low income and medically underinsured persons will continue to have access to all services provided by Fresenius related facilities.”

Considering all the information in the application, the applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on:

- Cost-effectiveness (see Sections C, F, N and Q of the application and any exhibits)
- Quality (see Sections C, N and O of the application and any exhibits)
- Access to medically underserved groups (see Sections L and N 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 based on 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.

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 59, 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.

10A NCAC 14C .2203 PERFORMANCE STANDARDS

(a) An applicant proposing to establish a new kidney disease treatment center or dialysis facility shall document the need for at least 10 dialysis stations based on utilization of 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the facility. An applicant may document the need for less than 10 stations if the application is submitted in response to an adjusted need determination in the State Medical Facilities Plan for less than 10 stations.

-NA- The applicant is not proposing to establish a new kidney disease treatment center or dialysis facility.

- (b) An applicant proposing to increase the number of dialysis stations in:*
 - (1) an existing dialysis facility; or*
 - (2) a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need;*

shall document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the additional stations.

-C- In Section Q, Form C, page 70, the applicant projects that FMC Northern Wake will serve 52 in-center patients on 18 stations, or a rate of 2.89 patients per station per week, as of the end of the first operating year following project completion. This exceeds the minimum performance standard of 2.8 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 68-71, the applicant provides the assumptions and methodology it used to project utilization of the facility.