

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: December 20, 2022

Findings Date: December 20, 2022

Project Analyst: Julie M. Faenza

Co-signer: Micheala Mitchell

Project ID #: J-12245-22

Facility: FMC Northern Wake

FID #: 130278

County: Wake

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

Project: Add no more than 2 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 20 dialysis stations upon project completion

REVIEW CRITERIA

G.S. 131E-183(a): The Department 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 “BMA” or “the applicant”) proposes to add two stations to FMC Northern Wake (FMC-NW) pursuant to Condition 2 of the facility need methodology for a total of 20 stations upon project completion.

Need Determination

Chapter 9 of the 2022 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 9C, on page 139 of the 2022 SMFP, 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 2022 SMFP, if the utilization rate

for the dialysis center as reported in the 2022 SMFP is at least 75 percent or 3.0 patients per station per week, as stated in Condition 2.a. Table 9A on page 132 of the 2022 SMFP shows the utilization rate reported for FMC-NW is 83.33% or 3.33 patients per station per week based on 60 dialysis patients and 18 certified dialysis stations (60 patients / 18 stations = 3.33; $3.33 / 4 = 83.33\%$).

As shown in Table 9D on page 141 of the 2022 SMFP, based on the facility need methodology for dialysis stations, the potential number of stations needed at FMC-NW is up to nine additional stations; thus, the applicant is eligible to apply to add up to nine stations during the 2022 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than two new stations to FMC-NW, which is consistent with the 2022 SMFP calculated facility need determination for up to nine 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 2022 SMFP which is applicable to this review. *Policy GEN-3: Basic Principles*, on page 30 of the 2022 SMFP, 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.”

In Section B, pages 21-23, the applicant explains why it believes its application is consistent with Policy GEN-3. On page 23, the applicant states:

“BMA projects utilization will continue to increase while the facility provides dialysis care and treatment in a safe environment, focused on quality patient care, and ensuring access to care for all patients with proper referral from a nephrology physician (patients cannot self-refer for dialysis treatment). The volume projections for this application are realistic and conservative. BMA consistently provides treatment for the medically underserved and does not discriminate in any manner; patients are accepted at the facility with proper referral from a physician with admitting privileges. The quality of care provided by the applicant is comparable with or exceeds industry standards for care.”

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 based on the following:

- The applicant adequately demonstrates that the application is consistent with Condition 2 of the facility need methodology as applied from the 2022 SMFP.
 - The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 based on the following:
 - The applicant adequately documents how the project will promote safety and quality in the delivery of ESRD services in Wake County.
 - The applicant adequately documents how the project will promote equitable access to ESRD services in Wake County.
 - The applicant adequately documents how the project will maximize healthcare value for the resources expended.
- (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, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to add two dialysis stations to FMC-NW pursuant to Condition 2 of the facility need methodology for a total of 20 stations following project completion.

In Section C, pages 25-26, the applicant states that it currently provides home hemodialysis and peritoneal dialysis training and support, and it plans to continue offering those modalities after project completion.

Patient Origin

On page 115, the 2022 SMFP defines the service area for dialysis stations as “...the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.” Thus, the service area for this facility consists of Wake County. Facilities may serve residents of counties not included in their service area.

The following tables illustrate current and projected patient origin.

FMC-NW Current Patient Origin – CY 2021						
	IC*		HH		PD	
	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients
Wake	49	86.0%	5	100.0%	14	93.3%
Franklin	7	12.3%	0	0.0%	1	6.7%
Vance	1	1.8%	0	0.0%	0	0.0%
Total	57	100.0%	5	100.0%	15	100.0%

Source: Section C, page 25

Note: Table may not foot due to rounding.

*In-Center

FMC-NW Projected Patient Origin – FY 2 (CY 2025)						
	IC*		HH		PD	
	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients
Wake	54.1	88.5%	5.5	100.0%	15.5	93.9%
Franklin	7.0	11.5%	0.0	0.0%	1.0	6.1%
Total	61.1	100.0%	5.5	100.0%	16.5	100.0%

Source: Section C, page 26

Note: Table may not foot due to rounding.

*In-Center

In Section C, pages 26-29, and immediately following Form C in Section Q, the applicant provides the assumptions and methodology used to project patient origin. The applicant’s assumptions are reasonable and adequately supported based on the following:

- The applicant clearly explains the growth projections for the Wake County patient population.
- The applicant did not project growth in the patient population dialyzing at or receiving home training and support at FMC-NW who do not live in Wake County.
- The applicant explains why the Vance County patient who was dialyzing at FMC-NW at the end of CY 2021 is not projected to continue being served at the facility.

Analysis of Need

In Section C, page 30, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

“Patients with End Stage Renal Disease require dialysis treatment on a regular and consistent basis in order to maintain life. Patients will normally receive three treatments per week. The NC SMFP recognizes that this patient population requires frequent and regular treatment. The need methodology for dialysis stations is focused on four patient shifts per week and recognizes that patients will generally dialyze on a Monday-Wednesday-Friday, morning or afternoon shift schedule, or on a Tuesday-Thursday-Saturday, morning or afternoon shift schedule. Failure to receive dialysis care will ultimately lead to the patient’s demise. The need that this population has for the proposed services is a function of the individual patient need for dialysis care and treatment.”

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

- According to the 2022 SMFP, as of December 31, 2020, FMC-NW was operating at a rate of 3.33 patients per station per week, or 83.33% of capacity.
- According to the Proposed 2023 SMFP, as of December 31, 2021, FMC-NW was operating at 79.17% of capacity, with a net loss of three patients between December 31, 2020 and December 31, 2021. However, despite that net loss of three patients, FMC-NW still shows a utilization rate above the utilization threshold needed to add stations, and shows a potential facility need of one station in the Proposed 2023 SMFP. The applicant uses the Wake County 5-Year Average Annual Change Rate (AACR) to project growth, and it is reasonable to believe that the combination of factors supports the need for two additional dialysis stations at FMC-NW.

Projected Utilization

In Section C, pages 25-26, and on Form C in Section Q, the applicant provides historical and projected utilization, as shown in the tables below.

FMC-NW Historical Utilization – CY 2021						
	IC*		HH		PD	
	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients
Wake	49	86.0%	5	100.0%	14	93.3%
Franklin	7	12.3%	0	0.0%	1	6.7%
Vance	1	1.8%	0	0.0%	0	0.0%
Total	57	100.0%	5	100.0%	15	100.0%

Note: Table may not foot due to rounding.

*In-Center

FMC-NW Projected Utilization – FY 2 (CY 2025)						
	IC*		HH		PD	
	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients
Wake	54.1	88.5%	5.5	100.0%	15.5	93.9%
Franklin	7.0	11.5%	0.0	0.0%	1.0	6.1%
Total	61.1	100.0%	5.5	100.0%	16.5	100.0%

Note: Table may not foot due to rounding.

*In-Center

In Section C, pages 26-29, and in the Form C Utilization subsection of Section Q, the applicant provides the assumptions and methodology used to project patient utilization, which are summarized below.

- The applicant begins its utilization projections with the in-center (IC) patient census at FMC-NW on December 31, 2021. The applicant states that on December 31, 2021, its IC patient census was comprised of 49 Wake County patients, 7 Franklin County patients, and 1 Vance County patient.
- The applicant projects growth in the Wake County IC patient population using the Wake County 5-year AACR of 2.5% as published in the 2022 SMFP.
- The applicant assumes no population growth for the IC patients residing in Franklin County but assumes the patients will continue to dialyze at FMC-NW and adds them to the calculations when appropriate.
- The applicant states the Vance County patient is no longer dialyzing at FMC-NW as of the date the application was submitted and does not include the Vance County patient in future projections.
- The project is scheduled to begin offering services on January 1, 2024. OY1 is CY 2024. OY2 is CY 2025.

In Section C, page 27, and immediately following Form C in Section Q, the applicant provides the calculations used to project the patient census for OY1 and OY2, as summarized in the table below.

FMC-NW IC Projected Utilization	
Starting point of calculations is Wake County IC patients dialyzing at FMC-NW on December 31, 2021.	49
Wake County IC patient population is projected forward by one year to December 31, 2022, using the 5-year AACR of 2.5%.	$49 \times 1.025 = 50.2$
Wake County IC patient population is projected forward by one year to December 31, 2023, using the 5-year AACR of 2.5%.	$50.2 \times 1.025 = 51.5$
The 7 Franklin County IC patients are added. This is the projected starting patient census on January 1, 2024.	$51.5 + 7 = 58.5$
Wake County IC patient population is projected forward by one year to December 31, 2024, using the 5-year AACR of 2.5%.	$51.5 \times 1.025 = 52.8$
The 7 Franklin County IC patients are added. This is the projected census on December 31, 2024 (OY1).	$52.8 + 7 = 59.8$
Wake County IC patient population is projected forward by one year to December 31, 2025, using the 5-year AACR of 2.5%.	$52.8 \times 1.025 = 54.1$
The 7 Franklin County IC patients are added. This is the projected census on December 31, 2025 (OY2).	$54.1 + 7 = 61.1$

The applicant projects to serve 59.8 patients on 20 stations, which is 3.0 patients per station per week ($59.8 \text{ patients} / 20 \text{ stations} = 2.99$, which is rounded to 3.0), by the end of OY1 and 61.1 patients on 20 stations, which is 3.1 patients per station per week ($61.1 \text{ patients} / 20 \text{ stations} = 3.06$, which is rounded to 3.1), by the end of OY2. This meets the minimum of 2.8 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

HH and PD Training

- The applicant begins its utilization projections with the HH and PD patient census at FMC-NW on December 31, 2021. The applicant states that on December 31, 2021, it was serving 5 HH patients and 14 PD patients from Wake County and one PD patient from Franklin County.
- The applicant projects growth in the Wake County patient populations using the 5-year AACR for Wake County of 2.5% as published in the 2022 SMFP.
- The applicant assumes no population growth for the Franklin County PD patient but assumes the patient will continue to be supported by the home training and support program and adds them to the calculations when appropriate.

In Section C, pages 28-29, and immediately following Form C in Section Q, the applicant provides the calculations used to project the HH and PD patient census for OY1 and OY2, as summarized in the table below.

FMC-NW HH & PD Projected Utilization		
	HH	PD
Starting point of calculations is Wake County HH & PD patients dialyzing or receiving support at FMC-NW on December 31, 2021.	5	14
Wake County HH & PD patient population is projected forward by one year to December 31, 2022, using the Wake County 5-year AACR (2.5%).	$5 \times 1.025 = 5.1$	$14 \times 1.025 = 14.4$
Wake County HH & PD patient population is projected forward by one year to December 31, 2023, using the Wake County 5-year AACR (2.5%).	$5.1 \times 1.025 = 5.3$	$14.4 \times 1.025 = 14.7$
The Franklin County PD patient is added. This is the projected starting census for the project as of January 1, 2024.		$14.7 + 1 = 15.7$
Wake County HH & PD patient population is projected forward by one year to December 31, 2024, using the Wake County 5-year AACR (2.5%).	$5.3 \times 1.025 = 5.4$	$14.7 \times 1.025 = 15.1$
The Franklin County PD patient is added. This is the projected census on December 31, 2024 (OY1).		$15.1 + 1 = 16.1$
Wake County HH & PD patient population is projected forward by one year to December 31, 2025, using the Wake County 5-year AACR (2.5%).	$5.4 \times 1.025 = 5.5$	$15.1 \times 1.025 = 15.5$
The Franklin County PD patient is added. This is the projected census on December 31, 2025 (OY2).		$15.5 + 1 = 16.5$

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

- FMC-NW was operating at a rate of 3.33 IC patients per station per week, or 83.33% of capacity, on December 31, 2021.
- The applicant projects growth in the Wake County patient population using the Wake County 5-year AACR as published in the 2022 SMFP.
- The applicant projects no growth for the Franklin County patients.

Access to Medically Underserved Groups

In Section C, page 33, the applicant states:

“.... Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, [people with disabilities], [people aged 65 and older], 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, or health insurer.

Fresenius Medical Care and its 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, [disability], age or any other grouping/category or basis for being an underserved person.”

The applicant provides the estimated percentage of total patients for each medically underserved group during the second full fiscal year, as shown in the following table.

Medically Underserved Groups	Estimated % of Total Patients in FY 2
Low income persons	15.66%
Racial and ethnic minorities	72.29%
Women	40.96%
Persons with disabilities	20.48%
Persons 65 and older	44.58%
Medicare beneficiaries	62.65%
Medicaid recipients	15.66%

Source: Section C, page 33

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The applicant provides a statement saying it will provide service to all residents of the service area, including underserved groups, without regard for anything other than the need for dialysis services.
- The applicant states the percentages of patients for each group listed above are based on recent facility experience.

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 all the reasons described above.

- (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, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose to reduce a service, eliminate a service, or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

The applicant proposes to add two dialysis stations to FMC-NW pursuant to Condition 2 of the facility need methodology for a total of 20 stations following project completion.

In Section E, page 42, 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 maintaining the status quo would result in higher utilization rates and potentially interrupt patient admissions, based on the Wake County 5-year AACR; therefore, this is not an effective alternative.
- Apply for More Than Two Stations: the applicant states that applying for more than two stations is not cost effective because the facility does not have room for more than 20 stations; therefore, this is not an effective alternative.

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 applicant provides reasonable information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

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. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. Pursuant to Condition 2 of the facility need determination in the 2022 SMFP, the certificate holder shall develop no more than 2 additional in-center dialysis stations for a total of no more than 20 in-center dialysis stations at FMC Northern Wake upon project completion.**

3. Progress Reports:

- a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.
 - b. The certificate holder shall complete all sections of the Progress Report form.
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.
 - d. The first progress report shall be due on June 1, 2023.
4. The certificate holder 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 two dialysis stations to FMC-NW pursuant to Condition 2 of the facility need methodology for a total of 20 stations following project completion.

Capital and Working Capital Costs

On Form F.1a in Section Q, the applicant projects the total capital cost of the project. The applicant projects to spend \$7,500 on non-medical equipment and furniture. Immediately following Form F.1a in Section Q, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions because the applicant explains what items are included in each category.

In Section F, page 45, the applicant states there are no projected start-up costs or initial operating expenses because FMC-NW is an existing and operational facility. This information is reasonable and adequately supported because FMC-NW is an existing facility currently offering ESRD services and will continue to offer ESRD services during and after development of the proposed project.

Availability of Funds

In Section F, pages 43-44, the applicant states the projected capital costs will be funded by accumulated reserves.

Exhibit F.2 contains a letter dated July 15, 2022 from the Senior Vice President & Treasurer of Fresenius Medical Care Holdings, Inc., the parent company of the applicant, authorizing the use of \$7,500 in cash reserves to develop the proposed project. The letter in Exhibit F.2 also states that the 2021 Consolidated Balance Sheet for Fresenius Medical Care Holdings, Inc. shows more than \$939 million in available cash and total assets of more than \$27.2 billion.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the following:

- The applicant provides a letter from a company executive authorizing the use of funding to develop the proposed project.
- The letter provides information to show that the applicant has adequate cash and assets available to fund the proposed project.

Financial Feasibility

The applicant provides pro forma financial statements for the first two full fiscal years of operation following completion of the project. On Form F.2 in Section Q, the applicant projects that revenues will exceed operating expenses in the first two full fiscal years following completion of the project, as shown in the table below.

Projected Revenues and Operating Expenses		
FMC-NW	FY 1 – CY 2024	FY 2 – CY 2025
Total Treatments	11,890	12,157
Total Gross Revenues (Charges)	\$74,797,842	\$76,481,575
Total Net Revenue	\$4,177,817	\$4,272,612
Average Net Revenue per Treatment	\$351	\$351
Total Operating Expenses (Costs)	\$3,088,270	\$3,142,538
Average Operating Expense per Treatment	\$260	\$258
Net Revenue/(Loss)	\$1,089,547	\$1,130,074

The assumptions used by the applicant in preparation of the pro forma financial statements are provided immediately following Form F.2 and in Forms F.3 and F.4 in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant adequately explains the assumptions used to project revenue, such as projected reimbursement rates, and operating costs, such as salaries.

- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which 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 for all the reasons described above.
 - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
 - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.
- (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 two dialysis stations to FMC-NW pursuant to Condition 2 of the facility need methodology for a total of 20 stations following project completion.

On page 115, the 2022 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 and Graham counties and Avery, Mitchell, and Yancey counties.*” Thus, the service area for this facility consists of Wake County. Facilities may serve residents of counties not included in their service area.

As of December 31, 2020, there were 20 existing or approved facilities providing dialysis and/or dialysis home training and support in Wake County. Information on these 20 existing and approved dialysis facilities is provided in the table below.

Wake County Dialysis Facilities Certified Stations and Utilization as of December 31, 2020				
Dialysis Facility	Owner	Location	# of Certified Stations	Utilization
BMA of Fuquay Varina Kidney Center	BMA	Fuquay Varina	29	84.48%
BMA of Raleigh Dialysis	BMA	Raleigh	50	85.00%
Cary Kidney Center	BMA	Cary	24	81.25%
FMC Eastern Wake	BMA	Rolesville	15	45.00%
FMC Morrisville	BMA	Cary	13	71.15%
FMC New Hope Dialysis	BMA	Raleigh	36	78.47%
FMC Northern Wake	BMA	Wake Forest	18	83.33%
FMC Wake Dialysis Clinic	BMA	Raleigh	50	105.00%
Fresenius Kidney Care Holly Springs	BMA	Holly Springs	10	55.00%
Fresenius Kidney Care Knightdale*	BMA	Knightdale	0	0.00%
Fresenius Medical Care Apex	BMA	Apex	20	68.75%
Fresenius Medical Care Central Raleigh	BMA	Raleigh	19	61.84%
Fresenius Medical Care Millbrook	BMA	Raleigh	17	85.29%
Fresenius Medical Care Rock Quarry*	BMA	Raleigh	0	0.00%
Fresenius Medical Care White Oak	BMA	Garner	16	95.31%
Southwest Wake County Dialysis	BMA	Raleigh	30	92.50%
Zebulon Kidney Center	BMA	Zebulon	30	71.67%
Downtown Raleigh Dialysis*	DaVita	Raleigh	0	0.00%
Oak City Dialysis	DaVita	Raleigh	10	80.00%
Wake Forest Dialysis Center	DaVita	Raleigh	21	101.19%

Source: Table 9A, Chapter 9, 2022 SMFP

*Facilities that are approved and under development but which are not yet operational.

In Section G, page 51, 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 based upon the facility performance and demonstrated need at the FMC Northern Wake facility. The need addressed by this application is not specific to Wake County as a whole.

...

..., only Fresenius Kidney Care Holly Springs, Fresenius Medical Care Central Raleigh and Zebulon Kidney Center were operating at less than 70% utilization. It is not uncommon for a facility to have lower utilization while another facility in the same county is well utilized. Facilities have been intentionally developed to place stations in close proximity to the patient residence; the intent is to provide dialysis treatment in convenient settings. While some capacity does exist at BMA facilities in Wake County, these facilities are not proximate to the FMC Northern Wake location. Within Raleigh and Wake County, traffic congestion is also a concern. Congestion leads to longer commute times, even when the travel distance may be relatively short. ... It is much more convenient for the patients to choose dialysis at the facility closest to their residence location as opposed to traveling further for the same dialysis care and treatment.”

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

- The applicant proposes to increase the number of dialysis stations in Wake County based on Condition 2 of the facility need determination in the 2022 SMFP.
- The applicant adequately demonstrates that the proposed dialysis stations are needed in addition to the existing or approved dialysis stations in Wake County.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

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

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

The applicant proposes to add two dialysis stations to FMC-NW pursuant to Condition 2 of the facility need methodology for a total of 20 stations following project completion.

On Form H in Section Q, the applicant provides current and projected staffing for the proposed services. The applicant does not project any change in staffing at FMC-NW as a result of the proposed project.

The assumptions and methodology used to project staffing are provided immediately following Form H in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.4 in Section Q. In Section H, pages 53-54, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant projects sufficient operating expenses for the staff proposed by the applicant.
- The applicant describes the required qualifications for staff, continuing education, and other training programs.

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 all the reasons described above.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

The applicant proposes to add two dialysis stations to FMC-NW pursuant to Condition 2 of the facility need methodology for a total of 20 stations following project completion.

Ancillary and Support Services

In Section I, page 55, the applicant identifies the necessary ancillary and support services for the proposed services. In Section I, pages 55-60, the applicant explains how each ancillary and support service is or will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The facility is an existing facility already providing the necessary ancillary and support services.
- The applicant describes the structure in place at both the corporate level and the facility level for providing the necessary ancillary and support services.

Coordination

In Section I, page 60, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit H-4. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The facility is an existing facility that has existing relationships with local health care and social service providers.
- The applicant provides a letter from the medical director of the facility attesting to the relationship between the medical director's physician practice and the facility.

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 all the reasons described above.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

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

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

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

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction

project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

The applicant does not propose to construct any new space or renovate any existing space. Therefore, Criterion (12) is not applicable to this review.

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and ... persons [with disabilities], 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 68, the applicant provides the historical payor mix during CY 2021 for its existing services, as shown in the table below.

FMC-NW Historical Payor Mix CY 2021						
	IC		HH		PD	
Payment Source	# of Patients	% of Patients	# of Patients	% of Patients	# of Patients	% of Patients
Self-Pay	0.6	1.05%	0.2	4.27%	0.2	1.19%
Commercial Insurance*	5.6	9.85%	1.2	24.01%	2.4	15.97%
Medicare*	45.1	79.08%	2.4	47.92%	12.2	81.03%
Medicaid*	2.5	4.46%	1.2	23.80%	0.0	0.00%
Misc. (including VA)	3.2	5.56%	0.0	0.00%	0.3	1.81%
Total	57.0	100.00%	5.0	100.00%	15.0	100.00%

*Including any managed care plans

Note: Table may not foot due to rounding.

In Section L, page 69, the applicant provides the following comparison.

	% of Total Patients Served by FMC-NW during CY 2021	% of the Population of Wake County
Female	41.0%	51.4%
Male	59.0%	48.6%
Unknown	0.0%	0.0%
64 and Younger	55.4%	88.0%
65 and Older	44.6%	12.0%
American Indian	0.0%	0.8%
Asian	0.0%	7.7%
Black or African-American	55.4%	21.0%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	33.7%	67.9%
Other Race	0.0%	13.0%
Declined / Unavailable	0.0%	0.0%

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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 ... persons [with disabilities] 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, in Section L, page 70, the applicant states it has no such obligation.

In Section L, page 70, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against FMC-NW.

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 71, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

FMC-NW Projected Payor Mix CY 2025						
	IC		HH		PD	
Payment Source	# of Patients	% of Patients	# of Patients	% of Patients	# of Patients	% of Patients
Self-Pay	0.6	1.05%	0.2	4.27%	0.2	1.19%
Commercial Insurance*	6.0	9.85%	1.3	24.01%	2.6	15.97%
Medicare*	48.3	79.08%	2.6	47.92%	13.3	81.03%
Medicaid*	2.7	4.46%	1.3	23.80%	0.0	0.00%
Misc. (including VA)	3.4	5.56%	0.0	0.00%	0.3	1.81%
Total	61.1	100.00%	5.5	100.00%	16.5	100.00%

*Including any managed care plans

Note: Table may not foot due to rounding.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 1.05% of IC services, 4.27% of HH services, and 1.19% of PD services will be provided to self-pay patients; 79.08% of IC services, 47.92% of HH services, and 81.03% of PD services will be provided to Medicare patients; and 4.46% of IC services and 23.80% of HH services will be provided to Medicaid patients.

On page 71, the applicant provides the assumptions and methodology it uses to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical payor mix at FMC-NW.

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 73, 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

The applicant proposes to add two dialysis stations to FMC-NW pursuant to Condition 2 of the facility need methodology for a total of 20 stations following project completion.

In Section M, page 74, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-2. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following:

- The applicant provides a copy of a letter sent to Wake Technical Community College offering the facility as a training site for nursing students.
- The applicant states it often receives calls to utilize the facility for health professional training programs and discusses the process for intake when it receives such an inquiry.

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 all the reasons described above.

- (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 two dialysis stations to FMC-NW pursuant to Condition 2 of the facility need methodology for a total of 20 stations following project completion.

On page 115, the 2022 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 and Graham counties and Avery, Mitchell, and Yancey counties.*” Thus, the service area for this facility consists of Wake County. Facilities may serve residents of counties not included in their service area.

As of December 31, 2020, there were 20 existing or approved facilities providing dialysis and/or dialysis home training and support in Wake County. Information on these 20 existing and approved dialysis facilities is provided in the table below.

Wake County Dialysis Facilities Certified Stations and Utilization as of December 31, 2020				
Dialysis Facility	Owner	Location	# of Certified Stations	Utilization
BMA of Fuquay Varina Kidney Center	BMA	Fuquay Varina	29	84.48%
BMA of Raleigh Dialysis	BMA	Raleigh	50	85.00%
Cary Kidney Center	BMA	Cary	24	81.25%
FMC Eastern Wake	BMA	Rolesville	15	45.00%
FMC Morrisville	BMA	Cary	13	71.15%
FMC New Hope Dialysis	BMA	Raleigh	36	78.47%
FMC Northern Wake	BMA	Wake Forest	18	83.33%
FMC Wake Dialysis Clinic	BMA	Raleigh	50	105.00%
Fresenius Kidney Care Holly Springs	BMA	Holly Springs	10	55.00%
Fresenius Kidney Care Knightdale*	BMA	Knightdale	0	0.00%
Fresenius Medical Care Apex	BMA	Apex	20	68.75%
Fresenius Medical Care Central Raleigh	BMA	Raleigh	19	61.84%
Fresenius Medical Care Millbrook	BMA	Raleigh	17	85.29%
Fresenius Medical Care Rock Quarry*	BMA	Raleigh	0	0.00%
Fresenius Medical Care White Oak	BMA	Garner	16	95.31%
Southwest Wake County Dialysis	BMA	Raleigh	30	92.50%
Zebulon Kidney Center	BMA	Zebulon	30	71.67%
Downtown Raleigh Dialysis*	DaVita	Raleigh	0	0.00%
Oak City Dialysis	DaVita	Raleigh	10	80.00%
Wake Forest Dialysis Center	DaVita	Raleigh	21	101.19%

Source: Table 9A, Chapter 9, 2022 SMFP

*Facilities that are approved and under development but which are not yet operational.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 75, 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.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 76, the applicant states:

“This is a proposal to add two stations to the FMC Northern wake (sic) 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 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.”

See also Sections C, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 76, the applicant states:

“Quality of care is always in the forefront at Fresenius Medical Care 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.”

See also Sections C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 75, the applicant states:

“All Fresenius Medical Care related facilities in North Carolina have a history of providing dialysis services to the underserved populations of North Carolina. Each of those facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, [people with disabilities], [people aged 65 and older], 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, 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, [disability], 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.”

See also Sections C and L of the application and any exhibits.

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, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant’s representations about how it will ensure the quality of the proposed services and the applicant’s record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant’s representations about access by medically underserved groups and the projected payor mix.

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 all the reasons described 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

The applicant proposes to add two dialysis stations to FMC-NW pursuant to Condition 2 of the facility need methodology for a total of 20 stations following project completion.

On Form O in Section Q, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 125 existing or approved kidney disease treatment facilities located in North Carolina.

In Section O, page 81, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents resulting in an Immediate Jeopardy violation that occurred in any of these facilities. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all 125 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.

G.S. 131E-183 (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 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- FMC-NW is an existing facility. Therefore, this Rule is not applicable to this review.

(b) *An applicant proposing to increase the number of dialysis stations in:*

(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 C, page 27, and on Form C in Section Q, the applicant projects that FMC-NW will serve 59.8 patients on 20 stations, or a rate of 3.0 patients per station per week, as of the end of the first operating year following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

-C- In Section C, pages 26-27, and immediately following Form C in Section Q, the applicant provides the assumptions and methodology it used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.