

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: May 1, 2023

Findings Date: May 1, 2023

Project Analyst: Ena Lightbourne

Co-Signer: Lisa Pittman

Project ID #: J-12311-23

Facility: Fresenius Kidney Care Eno River

FID #: 170324

County: Durham

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

Project: Relocate no more than 5 dialysis stations from FMC Briggs Avenue for a total of no more than 19 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.

NA

Bio-Medical Applications of North Carolina, Inc. (hereinafter referred to as “the applicant” or “BMA”), proposes to relocate five in-center dialysis stations from FMC Dialysis Services of Briggs Avenue (“FMC Briggs Avenue”) to Fresenius Kidney Care Eno River (“FKC Eno River”), for a total of no more than 19 in-center dialysis stations at FKC Eno River and 24 dialysis stations at FMC Briggs Avenue upon project completion.

Chapter 9 of the 2023 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, page 132, the county need methodology shows there is no county need determination for additional dialysis stations in Durham County. The applicant is proposing to relocate existing dialysis stations. Therefore, neither of the two need determination methodologies in the 2023 SMFP apply to this proposal.

The applicant does not propose to:

- Develop any beds or services for which there is a need determination in the 2023 State Medical Facilities Plan (SMFP).
- Acquire any medical equipment for which there is a need determination in the 2023 SMFP.
- Offer a new institutional health service for which there are any applicable policies in the 2023 SMFP.

Therefore, Criterion (1) is not applicable to this review.

- (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 relocate five in-center dialysis stations from FMC Briggs Avenue to FKC Eno River for a total of no more than 19 in-center dialysis stations upon project completion.

The following table, summarized from data on pages 15 and 36 of the application, shows the projected number of stations at FKC Eno River and FMC Briggs Avenue upon project completion.

FKC Eno River		
Stations	Description	Project ID #
14	Total # of existing certified stations as reported in the most recent ESRD Data Collection Forms.	
+5	Stations to be added as part of this project (relocate 5 in-center dialysis stations from FMC Briggs Avenue).	J-12311-23
19	Total # of dialysis stations upon project completion.	

FMC Briggs Avenue		
Stations	Description	Project ID #
29	Total # of existing certified stations as reported in the most recent ESRD Data Collection Forms.	
-5	Stations to be relocated as part of this project (relocate 5 in-center dialysis stations from FMC Briggs Avenue).	J-12311-23
24	Total # of dialysis stations upon project completion.	

Patient Origin

On page 113, the 2023 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located.*” Thus, the service area for this facility consists of Durham County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates historical and projected patient origin.

FKC Eno River Historical and Projected Patient Origin				
County	Last Full FY 1/1/2022- 12/31/2022 (CY 2022)		Second Full FY 1/1/2025-12/31/2025 (CY 2025)	
	# of In- Center Patients	% of Total	# of In- Center Patients	% of Total
Durham	41.0	89.1%	59.2	92.2%
Graham	1.0	2.2%	1.0	1.6%
Orange	2.0	4.3%	2.0	3.1%
Person	1.0	2.2%	1.0	1.6%
Wake	1.0	2.2%	1.0	1.6%
Total	46.0	100.0%	64.2	100.0%

Source: Section C, pages 23-24

In Section C, pages 24-25, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported based on the following:

- Since the facility began operations in December 2020, FKC Eno River experienced a growth in the patient population that was higher than the Durham County Five-Year Average Annual Change Rate (AACR) of 0.03%, as published in the 2023 SMFP.
- The applicant projects patient population forward using a conservative growth rate higher than the Durham County Five-Year AACR but significantly lower than the historical growth.

Analysis of Need

In Section C, page 27, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 27, the applicant states:

“The need that this population has for the proposed services is a function of the individual patient need for dialysis care and treatment. This question specifically addresses the need that the population to be served has for the proposed project. The applicant has identified the population to be served as 57.4 in-center dialysis patients dialyzing with the facility as of the end of the first Operating Year of the project. This

equates to a utilization rate of 75.46%, or 3.02 patients per station and exceeds the minimum required by the performance standard.”

The information is reasonable and adequately supported based on the FKC Eno River’s historical growth in the patient population.

Projected Utilization

In Section Q, page 82, the applicant provides projected utilization, as illustrated in the following table.

Form C Utilization	Last Full FY CY 2021	Interim Full FY CY 2022	Interim Full FY CY 2023	1st Full FY CY 2024	2nd Full FY CY 2025
In-Center Patients					
# of Patients at the Beginning of the Year	1	36	46	51	57
# of Patients at the End of the Year	36	46	51	57	64
Average # of Patients during the Year	19	41	49	54	61
# of In-center Treatments / Patient / Year	148	148	148	148	148
Total # of Treatments	4,351	6,068	7,202	8,043	8,992

In Section C, pages 24-26 and Section Q, pages 83-85, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The applicant begins its projections with the facility’s patient census as of December 31, 2022, as reported in the 2022 ESRD Data Collection Forms submitted to the Agency. The facility served a total of 46 in-center patients and of those patients, 41 resided in Durham County. The facility operated at 3.29 patients per station or 82.14% utilization.
- The applicant illustrates the historical growth in the patient census since FKC Eno River began operations in December 2020.

FKC Eno River Facility Census		
	2022 SMFP	2023 SMFP
	12/31/2020	12/31/2021
Durham County Patients	1	31
Non-Durham Patients	0	5
Total Patients	1	36

Source: Section C, page 24

As illustrated in the table above, both the Durham County and the total facility patient population more than doubled since the opening of the facility. The Durham County patient population increased by 32.3% between December 31, 2021 and December 31, 2022. The

applicant states that the facility admitted 10 new Durham County in-center patients during that time.

- The applicant projects growth of the Durham County patient population using a growth rate of 13.0%, which is significantly higher than the Durham County Five-Year AACR of 0.3%, as published in the 2023 SMFP. The applicant states that using a growth rate of 13.0% is conservative considering the 32.3% historical growth of the Durham County patient population at FKC Eno River.
- The facility served five patients residing in Granville, Orange, Person and Wake counties, which are all contiguous to Durham County. The applicant assumes that these patients will continue dialysis at FKC Eno River out of choice. The applicant does not project any growth for this segment of the patient population and adds these patients to its projections at the appropriate time.
- The applicant projects the first operating year (OY) of the project will be January 1, 2024-December 31, 2024 and the second operating year (OY) will be January 1, 2025-December 31, 2025.

FKC Eno River	In-Center patients
Begin with the Durham County patient population as of December 31, 2022.	41
Project the Durham County patient population forward for one year to December 31, 2023, using a 13.0% growth rate based on the facility's historical performance.	$41.0 \times 1.13 = 46.3$
Add the five patients from other counties. This is the projected ending census for Interim Year 1.	$46.3 + 5 = 51.3$
Project the Durham County patient population forward for one year to December 31, 2024, using a 13.0% growth rate based on the facility's historical performance.	$46.3 \times 1.13 = 52.4$
Add the five patients from other counties. This is the projected ending census for Operating Year 1.	$52.4 + 5 = 57.4$
Project the Durham County patient population forward for one year to December 31, 2025, using a 13.0% growth rate based on the facility's historical performance.	$52.4 \times 1.13 = 59.2$
Add the five patients from other counties. This is the projected ending census for Operating Year 2.	$59.2 + 5 = 64.2$

Source: Section C, page 26 and Section Q, page 85

FKC Eno River is projected to serve 57.4 in-center patients at the end of OY1 and 64.2 in-center patients at the end of OY2 on a total of 19 stations.

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

- OY1: 3.0 patients per station per week or 75.52% (57.4 patients / 19 stations = 3.021/4 = 0.7552 or 75.52%)
- OY2: 3.3 patients per station per week or 82.78% (64.2 patients / 19 stations = 3.378/4 = 0.8445 or 84.45%)

The projected utilization of 3.0 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 based on the following:

- The applicant demonstrates the need for the additional stations at FKC Eno River based on the facility's historical growth in patient population, which was significantly higher than the Durham County Five-Year AACR of 0.03%.
- Projected utilization at the end of OY1 exceeds the minimum of 2.8 IC patients per station per week required by 10A NCAC 14C .2203(b).

Access to Medically Underserved Groups

In Section C, page 30, the applicant states:

“Fresenius Medical Care operates more than 100 dialysis facilities across North Carolina. 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.

...

...Medicare (includes Medicare Advantage treatments) represented 77.87% of North Carolina dialysis treatments in Fresenius related facilities in FY 2021; Medicaid treatments represented an additional 6.87% of treatments in our facilities for FY 2021.

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low income persons	30.4%
Racial and ethnic minorities	91.3%
Women	39.1%
Persons with disabilities	30.4%
Persons 65 and older	50.0%
Medicare beneficiaries	93.5%
Medicaid recipients	30.4%

Source: Section C, page 30

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. The applicant operates five dialysis facilities in Durham County currently providing services to underserved groups.

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.

C

The applicant proposes to relocate five in-center dialysis stations from FMC Briggs Avenue to FKC Eno River for a total of no more than 19 in-center dialysis stations upon project completion.

The following table shows the projected number of stations at FMC Briggs Avenue upon project completion.

FMC Briggs Avenue		
Stations	Description	Project ID #
29	Total # of existing certified stations as reported in the most recent ESRD Data Collection Forms.	
-5	Stations to be relocated as part of this project (relocate 5 in-center dialysis stations from FMC Briggs Avenue).	J-12311-23
24	Total # of dialysis stations upon project completion.	

Source: Section C, page 36

In Section D, page 38, the applicant explains why it believes the needs of the population presently utilizing the services to be relocated will be adequately met following completion of the project. On page 38, the applicant states:

“BMA notes that Table 9D: Determination Station Need Determination by Facility in the 2023 SMFP indicates that FMC Briggs Avenue is eligible to apply for up to five additional stations in 2023. BMA intends to apply for five stations to replace the stations being relocated to FKC Eno River. FMC Briggs Avenue intends to apply for the five stations on March 15, 2023, for the review planned to begin on April 1, 2023.”

The information is reasonable and adequately supported based on the following:

- The applicant projects that FMC Briggs Avenue will have 95% utilization on 24 dialysis stations by the end of December 31, 2023.
- According to Table 9D on page 136 of the 2023 SMFP, FMC Briggs Avenue is eligible to apply for up to five dialysis stations.

In Section Q, page 86, the applicant provides projected utilization, as illustrated in the following table.

FMC Briggs Avenue					
Form C Utilization	Last Full FY CY 2022	Interim Full FY CY 2023	1st Full FY CY 2024	2nd Full FY CY 2025	Utilization on Date Stations are Relocated 12/31/2023
In-Center Patients					
# of Patients at the Beginning of the Year	100	92	91	91	91
# of Patients at the End of the Year	92	91	91	92	
Average # of Patients during the Year	96	92	91	92	
Total Patients					
# of Patients at the Beginning of the Year	100	92	91	91	Total Patients 91
# of Patients at the End of the Year	92	91	91	92	
Average # of Patients during the Year	96	92	91	92	

In Section D, pages 36-38 and Section Q, pages 86-89, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The applicant begins its projections with the facility patient population as of December 31, 2022, as reported in the 2022 ESRD Data Collection Forms submitted to the Agency.

FMC Briggs Avenue	December 31, 2022
	In-Center patients
Durham	83
Johnston	1
Orange	1
Wake	7
Total	92

Source: Section Q, page 87

- The applicant projects growth of the Durham County patient population using the Durham County Five-Year AACR of 0.03%, as published in the 2023 SMFP.
- The facility served nine patients residing in Johnston, Orange, and Wake counties. Orange, and Wake counties are contiguous to Durham County. The applicant assumes that these patients will continue to dialyze at FMC Briggs Avenue out of choice. The applicant does not project any growth for this segment of the patient population and adds these patients to projections at the appropriate time.
- The one Johnston County patient was at rehabilitation in Durham County and plans to return to Johnston County. The applicant counted this patient in the patient census because the patient was at the facility for more than 30 days. The patient was not counted in future projections.
- The relocated stations are projected to be certified as of December 31, 2023.

FMC Briggs Avenue	In-Center patients
Begin with the Durham County patient population as of December 31, 2022.	83
Project the Durham County patient population forward to December 31, 2023, using the Durham County Five-Year AACR of 0.03%.	$83 \times 1.003 = 83.2$
Add the eight patients from Orange and Wake counties. This is the projected census for the date the stations are projected to be relocated.	$83.2 + 8 = 91.2$
The remaining calculations are for completion of the Form D Utilization only. The information is not relevant for determining conformity with CON Review Criterion 3a.	
Project the Durham County patient population forward for to December 31, 2024, using the Durham County Five-Year AACR of 0.03%	$83.2 \times 1.003 = 83.5$
Add the eight patients from Orange and Wake counties. This is the projected ending census for Operating Year 1.	$83.5 + 8 = 91.5$
Project the Durham County patient population forward to December 31, 2025, using the Durham County Five-Year AACR of 0.03%	$83.5 \times 1.003 = 83.7$
Add the five patients from other counties. This is the projected ending census for Operating Year 2.	$83.7 + 8 = 91.7$

Source: Section D, pages 37-38 and Section Q, page 88

As of December 31, 2023, FMC Briggs Avenue is projected to serve 91.2 in-center patients on 24 dialysis stations. The projected utilization rates are as follows:

3.8 patients per station per week or 95.00% ($91.2 \text{ patients} / 24 \text{ stations} = 3.80/4 = 0.9500$ or 95.00%).

Projected utilization is reasonable and adequately supported based on the following:

- The applicant projects utilization using the Durham County Five-Year AACR.
- The applicant projects that FMC Briggs Avenue will have 95% utilization on 24 dialysis stations by the end of December 31, 2023.
- According to Table 9D on page 136 of the 2023 SMFP, FMC Briggs Avenue is eligible to apply for up to five stations.

Access to Medically Underserved Groups

In Section D, page 39, the applicant states:

“BMA has a long history of providing dialysis services to the underserved populations of North Carolina. 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, or health insurer.”

The applicant adequately demonstrates that the needs of medically underserved groups that will continue to use dialysis services will be adequately met following completion of the project.

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 demonstrates that the needs of the population currently using the services to be reduced, eliminated or relocated will be adequately met following project completion for all the reasons described above.
- The applicant adequately demonstrates that the project will not adversely impact the ability of underserved groups to access these services following project completion for all the reasons described above.

- (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.

C

The applicant proposes to relocate five in-center dialysis stations from FMC Briggs Avenue to FKC Eno River for a total of no more than 19 in-center dialysis stations upon project completion.

In Section E, page 41, 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 this alternative was dismissed because not applying for stations would ultimately result in high utilization at FKC Eno River. The applicant states that if the stations are not relocated, utilization on 14 stations is projected to be 4.10 patients per station by the end of the first operating year.

Relocate fewer than five stations-The applicant states that utilization rates will increase as the patient census increase. This alternative was dismissed for the same reason as maintaining the status quo.

On page 41, the applicant states that its proposal is the most effective alternative because it will avoid higher utilization rates that can disrupt patient admissions.

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

- The facility's need to expand capacity as the patient census continues grows.
- 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

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. The certificate holder shall relocate no more than five in-center dialysis stations to Fresenius Kidney Care Eno River for a total of 19 in-center stations upon project completion.**
- 3. Upon completion of this project, the certificate holder shall take the necessary steps to decertify five in-center dialysis stations from FMC Dialysis Services of Briggs Avenue for a total of no more than 24 in-center stations.**
- 4. 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 is due on November 1, 2023.**

5. 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 relocate five in-center dialysis stations from FMC Briggs Avenue for a total of no more than 19 in-center dialysis stations upon completion.

Capital and Working Capital Costs

In Section Q, page 90, the applicant projects the total capital cost of the project, as shown in the table below.

FKC Eno River Projected Capital Cost	
Non-Medical Equipment	\$3,750
Furniture	\$15,000
Total	\$18,750

In Section Q, page 91, 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 based on the following:

- The applicant projects capital costs based on the necessary furniture and non-medical equipment for operation of the facility.
- The applicant identified non-medical equipment costs as water treatment system for dialysis operations, signs, project communications and ancillary medical equipment.

In Section F, page 44, the applicant states that there are no start-up or initial operating costs associated with an operational facility.

Availability of Funds

In Section F, page 42, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing

Type	BMA	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$18,750	\$18,750
Bonds	\$0	\$0
Other	\$0	\$0
Total Financing	\$18,750	\$18,750

* OE = Owner's Equity

Exhibit F-2 contains a letter dated January 17, 2023, from the Senior Vice President and Treasurer of Fresenius Medical Care Holdings, Inc. stating their commitment to fund the project with accumulated reserves. The letter states that 2020 consolidated financial statements for Fresenius Medical Care Holdings, Inc. state more than \$446 million in cash and over \$25 billion in total assets to fund the project.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the information provided in Section F and Exhibit F-2 of the application.

Financial Feasibility

The applicant provided pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Form F.2, 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.

FKC Eno River	1 st Full FY CY2024	2 nd Full FY CY2025
Total Treatments	8,043	8,992
Total Gross Revenues (Charges)	\$50,595,585	\$56,567,817
Total Net Revenue	\$2,730,554	\$3,052,864
Average Net Revenue per Treatment	\$340	\$340
Total Operating Expenses (Costs)	\$2,268,792	\$2,381,810
Average Operating Expense per Treatment	\$282	\$265
Net Income	\$461,762	\$671,054

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q, pages 94 -100. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant provides reasonable assumptions in determining revenue and operating expenses in preparation of Form F.2, F.3 and F.4.

- 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 relocate five in-center dialysis stations from FMC Briggs Avenue to FKC Eno River for a total of no more than 19 in-center dialysis stations upon project completion.

On page 113, the 2023 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located.*” Thus, the service area for this facility consists of Durham County. Facilities may also serve residents of counties not included in their service area.

The table below lists the existing and approved facilities, certified stations, and utilization of dialysis facilities in Durham County as of December 31, 2021. There were 13 kidney disease treatment centers providing dialysis services in Durham County. The applicant operated five dialysis facilities in the service area.

Facility Name	Certified Stations as of 12/31/2021	# IC Patients as of 12/31/2021	Utilization by Percent as of 12/31/2021	Patients Per Station Per Week
Bull City Dialysis	16	55	85.94%	3.43
Downtown Durham Dialysis	10	10	25.00%	1.00
Durham Dialysis	29	91	78.45%	3.13
Durham Regional Dialysis	10	18	45.00%	1.80
Durham West Dialysis	27	74	68.52%	2.74
FMC Dialysis Services of Briggs Avenue	29	100	86.21%	3.44
FMC Dialysis Services West Pettigrew	24	58	60.42%	2.41
Freedom Lake Dialysis Center	26	61	58.65%	2.34
Fresenius Kidney Care Eno River	14	36	64.29%	2.57
Fresenius Medical Care South Durham Dialysis	20	63	78.75%	3.15
Hope Valley Dialysis	10	19	47.50%	1.90
Research Triangle Park Dialysis	10	19	47.50%	1.90
Southpoint Dialysis	16	58	90.63%	3.62
Total	241	662		

Source: 2023 SMFP, Table 9A, pages 121-122

In Section G, page 50, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Durham County. The applicant states:

“The applicant is not proposing to develop new dialysis stations by this proposal. The applicant proposes to relocate existing certified dialysis stations within Durham County. These stations have been previously approved and do not duplicate existing or approved services.

BMA owns and operates a total of five dialysis facilities in Durham County. Three of those facilities, FKC Eno River, FMC Briggs Avenue and FMC South Durham Dialysis were operating well above 70% utilization...”

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

- The proposal would not result in an increase in dialysis stations in the service area because the applicant is proposing to relocate existing dialysis stations.
- The applicant's proposal would not result in unnecessary duplication based on the high utilization of the existing dialysis facilities in the service area owned and operated by the applicant.

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.

- (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 relocate five in-center dialysis stations from FMC Briggs Avenue to FKC Eno River for a total of no more than 19 in-center dialysis stations upon project completion.

In Section Q, page 101, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

	Current Staff	Projected FTE Staff	
	as of 12/15/2021	1 st Full FY CY 2024	2 nd Full FY CY 2025
Administrator (FMC Clinic Manager)	1.00	1.00	1.00
Registered Nurses (RNs)	2.00	2.00	2.00
Technicians (PCT)	4.50	4.50	4.50
Dietician	0.50	0.50	0.50
Social Worker	0.50	0.50	0.50
Maintenance	0.75	0.75	0.75
Administration/Business Office	1.00	1.00	1.00
Other (FMC Director of Operations)	0.14	0.14	0.14
Other (FMC Chief Technician)	0.13	0.13	0.13
Other (FMC in-service)	0.13	0.13	0.13
TOTAL	10.65	10.65	10.65

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.4. In Section H, pages 51-52, 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 is an established provider of dialysis services in the service area and has a long history of recruiting appropriate staff.
- New staff are required to complete a 10-week training program that includes clinical aspects of the job and training on corporate policies and procedures.

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 relocate five in-center dialysis stations from FMC Briggs Avenue to FKC Eno River for a total of no more than 19 in-center dialysis stations upon project completion.

Ancillary and Support Services

In Section I, page 53, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 53-58, 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.

Coordination

In Section I, page 58, 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 based on the following:

- The applicant has an informal relationship with Carolina Vascular Access, where patients have access to surgeries and dialysis-related care.
- The applicant established relationships with other physicians and hospitals in the area and has agreements in place for lab services, hospital affiliation and transplant.

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, pages 66-67, the applicant provides the historical payor mix during CY 2021 for the proposed services, as shown in the table below.

FKC Eno River Historical Payor Mix, Last Full FY 01/01/2021 to 12/30/2021		
Payor Category	In-Center Patients	% of Total
Self-Pay	0.4	1.12%
Insurance *	2.6	7.32%
Medicare*	31.2	86.62%
Medicaid*	0.2	0.57%
Other (Misc. including VA)	1.6	4.36%
Total	36.0	100.00%

*Including any managed care plans.

FMC Briggs Avenue Historical Payor Mix, Last Full FY 01/01/2021 to 12/30/2021		
Payor Category	In-Center Patients	% of Total
Self-Pay	2.6	2.55%
Insurance *	7.6	7.57%
Medicare*	80.6	80.57%
Medicaid*	7.2	7.20%
Other (Misc. including VA)	2.1	2.11%
Total	100.0	100.00%

*Including any managed care plans.

In Section L, pages 67-68, the applicant provides the following comparison.

FKC Eno River	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area*
Female	43.0%	52.2%
Male	57.0%	47.8%
Unknown	0.0%	0.0%
64 and Younger	30.0%	85.7%
65 and Older	70.0%	14.3%
American Indian	0.0%	1.0%
Asian	7.0%	5.6%
Black or African-American	47.0%	35.9%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	53.0%	43.4%
Other Race	0.0%	16.6%
Declined / Unavailable	0.0%	0.0%

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

FMC Briggs Avenue	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area*
Female	37.0%	52.2%
Male	63.0%	47.8%
Unknown	0.0%	0.0%
64 and Younger	38.0%	85.7%
65 and Older	62.0%	14.3%
American Indian	0.0%	1.0%
Asian	0.0%	5.6%
Black or African-American	77.2%	35.9%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	18.5%	43.4%
Other Race	0.0%	16.6%
Declined / Unavailable	0.0%	0.0%

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

The Agency reviewed the:

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

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and ... 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 68, the applicant states:

“Not applicable. The facility is not obligated under any applicable federal regulations to provide uncompensated care, community service, or access by minorities and persons with disabilities.”

In Section L, page 68, the applicant states that during the 18 months immediately preceding the application deadline, 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.

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

FKC Eno River Projected Payor Mix 2nd Full FY, CY 2025		
Payor Category	In-Center Patients	% of Total
Self-Pay	0.7	1.12%
Insurance *	4.7	7.32%
Medicare*	55.6	86.62%
Medicaid*	0.4	0.57%
Other (Misc. including VA)	2.8	4.36%
Total	64.2	100.00%

*Including any managed care plans.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 1.12% of total services will be provided to self-pay patients, 86.62% to Medicare patients and 0.57% to Medicaid patients.

On page 69, the applicant provides the assumptions and methodology used 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 based on the following:

- The applicant calculates payor mix based upon treatment volumes as opposed to the number of patients. The applicant considers possible changes in payor source during the fiscal year.
- Payor mix projections are based on recent facility performance.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated above.

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

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 relocate five in-center dialysis stations from FMC Briggs Avenue to FKC Eno River for a total of no more than 19 in-center dialysis stations upon project completion.

In Section M, page 72, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-1. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following:

- FKC Eno River has an existing agreement with Durham Technical College Nursing Program.
- The facility provides onsite educational experiences to local training programs in the service area.

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 relocate five in-center dialysis stations from FMC Briggs Avenue to FKC Eno River for a total of no more than 19 in-center dialysis stations upon project completion.

On page 113, the 2023 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located.*” Thus, the service area for this facility consists of Durham County. Facilities may also serve residents of counties not included in their service area.

The table below lists the existing and approved facilities, certified stations, and utilization of dialysis facilities in Durham County as of December 31, 2021. There were 13 kidney disease treatment centers providing dialysis services in Durham County. The applicant operated five dialysis facilities in the service area.

Facility Name	Certified Stations as of 12/31/2021	# IC Patients as of 12/31/2021	Utilization by Percent as of 12/31/2021	Patients Per Station Per Week
Bull City Dialysis	16	55	85.94%	3.43
Downtown Durham Dialysis	10	10	25.00%	1.00
Durham Dialysis	29	91	78.45%	3.13
Durham Regional Dialysis	10	18	45.00%	1.80
Durham West Dialysis	27	74	68.52%	2.74
FMC Dialysis Services of Briggs Avenue	29	100	86.21%	3.44
FMC Dialysis Services West Pettigrew	24	58	60.42%	2.41
Freedom Lake Dialysis Center	26	61	58.65%	2.34
Fresenius Kidney Care Eno River	14	36	64.29%	2.57
Fresenius Medical Care South Durham Dialysis	20	63	78.75%	3.15
Hope Valley Dialysis	10	19	47.50%	1.90
Research Triangle Park Dialysis	10	19	47.50%	1.90
Southpoint Dialysis	16	58	90.63%	3.62
Total	241	662		

Source: 2023 SMFP, Table 9A, pages 121-122

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 73, the applicant states:

“The applicant does not project to serve dialysis patients currently being served by another provider.

...

With this application, the applicant seeks the opportunity to continue providing dialysis care and treatment to the patients of the area who have expressed their desire to receive dialysis care and treatment at FKC Eno River.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 74, the applicant states:

“...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 74, the applicant states:

“Quality of care is always in the forefront at Fresenius Medical Care related facilities...Fresenius Medical Care, parent organization for this facility, expects every facility to provide high quality care to every patient at every treatment.”

See also Section O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 74, the applicant states:

“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.”

See also Sections L and C 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.
- 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 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

In Section Q, pages 103-107, 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 of this type of facility located in North Carolina.

In Section O, page 79, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to immediate jeopardy had not occurred in any of these facilities. After reviewing and considering information provided by the applicant, the applicant provided 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

10A NCAC 14C .2203 PERFORMANCE STANDARDS

- (a) *An applicant proposing to establish a new dialysis facility for in-center hemodialysis services 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 full fiscal year of operation following certification of the facility. An applicant may document the need for fewer than 10 stations if the application is submitted in response to an adjusted need determination in the State Medical Facilities Plan for fewer than 10 stations.*

-NA- The applicant is not proposing to establish a new dialysis facility.

- (b) *An applicant proposing to increase the number of in-center 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 full fiscal year of operation following certification of the additional stations.*
- C- In Section C, page 26 and Section Q, page 85, the applicant projects that FKC Eno River will serve 57.4 in-center patients on 19 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 proposing to establish a new dialysis facility dedicated to home hemodialysis or peritoneal dialysis training shall document the need for the total number of home hemodialysis stations in the facility based on training six home hemodialysis patients per station per year as of the end of the first full fiscal year of operation following certification of the facility.*
- NA- The applicant is not proposing to establish a new dialysis facility dedicated to home hemodialysis or peritoneal dialysis training.
- (d) *An applicant proposing to increase the number of home hemodialysis stations in a dialysis facility dedicated to home hemodialysis or peritoneal dialysis training shall document the need for the total number of home hemodialysis stations in the facility based on training six home hemodialysis patients per station per year as of the end of the first full fiscal year of operation following certification of the additional stations.*
- NA- The applicant is not proposing to increase the number of home hemodialysis stations in a dialysis facility dedicated to home hemodialysis or peritoneal dialysis training.
- (e) *The applicant shall provide the assumptions and methodology used for the projected utilization required by this Rule.*
- C- In Section C, pages 24-26, and Section Q, pages 83-85, the applicant provides the assumptions and methodology it uses to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.