

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: June 20, 2025

Findings Date: June 20, 2025

Project Analyst: Cynthia Bradford

Co-Signer: Lisa Pittman

Project ID #: J-12584-25

Facility: Fresenius Kidney Care Butner Dialysis

FID #: 250046

County: Granville

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

Project: Develop a new dialysis facility by relocating no more than 6 dialysis stations from FMC Dialysis Services of Oxford and no more than 7 dialysis stations from FMC Dialysis Services Neuse River for a total of no more than 13 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”, Fresenius Kidney Care Butner Dialysis or FKC Butner Dialysis) proposes to develop a new dialysis facility by relocating no more than six dialysis stations from FMC Dialysis Services of Oxford and no more than seven dialysis stations from FMC Dialysis Services Neuse River for a total of no more than 13 stations upon project completion

The applicant does not propose to develop any beds or services or acquire any medical equipment for which there is a need determination in the 2025 SMFP or offer a new

institutional health service for which there are any applicable policies in the 2025 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- (2) Repealed effective July 1, 1987.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 develop a new 13-station dialysis facility by relocating no more than six dialysis stations from FMC Dialysis Services of Oxford and no more than seven dialysis stations from FMC Dialysis Services of Neuse River.

**Patient Origin**

On page 113, the 2025 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 Granville County. Facilities may serve residents of counties not included in their service area.

The proposed project is for a new facility with no historical patient origin data. The following tables illustrate the historical patient origin for the existing dialysis stations that will be relocated from FMC Oxford and FMC Neuse River as part of this proposal:

FMC Oxford Historical Patient Origin						
Last Full FY						
CY 2024						
County	# IC Patients	% Total	# HH Patients	% Total	# PD Patients	% Total
Granville	52.0	66.7%				66.7%
Durham	1.0	1.3%				1.3%
Franklin	1.0	1.3%				1.3%
Mecklenburg	4.0	5.1%				5.1%
Person	1.0	1.3%				1.3%
Vance	18.0	23.1%				23.1%
Warren	1.0	1.3%				1.3%
<b>Total</b>	<b>78.0</b>	<b>100.0%</b>				<b>100.0%</b>

Source: Supplemental information

FMC Neuse River Historical Patient Origin Last Full FY CY 2024						
County	# IC Patients	% Total	# HH Patients	% Total	# PD Patients	% Total
Granville	67.0	78.8%	2.0	50.0%	3.0	75.0%
Franklin	2.0	2.4%	0.0	0.0%	1.0	25.0%
Person	1.0	1.2%	1.0	25.0%	0.0	0.0%
Vance	13.0	15.3%	0.0	0.0%	0.0	0.0%
Virginia	0.0	0.0	1.0	25.0%	0.0	0.0%
Warren	2.0	2.4%	0.0	0.0%	0.0	0.0%
<b>Total</b>	<b>85.0</b>	<b>100.0%</b>	<b>4.0</b>	<b>100.0%</b>	<b>4.0</b>	<b>100.0%</b>

Source: Section C, page 23

The following table illustrates projected patient origin for the proposed FKC Butner Dialysis facility.

FKC Butner Dialysis Projected Patient Origin Second Full FY CY 2029						
County	#IC Patients	% Total	#HH Patients	% Total	# PD Patients	%Total
Granville	40.7	100.0%	0	0%	0	0%
<b>Total</b>	<b>40.7</b>	<b>100.0%</b>	<b>0</b>	<b>0%</b>	<b>0</b>	<b>0%</b>

Source: Section C, page 24

In Section C, page 24, the applicant provides the assumptions and methodology used to project patient origin. The applicant's assumptions are reasonable and adequately supported because they are based on the patient origin for forty (40) in-center patients who currently receive their dialysis treatments in Fresenius operated facilities in Granville County and who live in Granville County and have signed letters indicating they would consider transfer to FKC Butner Dialysis.

The following table summarizes the breakdown of the patient letters detailed above:

ZIP Code of Patient Residence	FMC Oxford	FMC Neuse River	Total
27509	2	5	7
27522	3	11	14
27565	18	0	18
27582	0	1	1
<b>Total</b>	<b>23</b>	<b>17</b>	<b>40</b>

Source: Application, page 24

### **Analysis of Need**

In Section C, pages 26-27, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below.

*“Dialysis can be a very time-consuming and physically demanding process and sometimes a difference of just a few minutes of travel time can make a*

*significant difference to an individual patient. Forty (40) Granville County in-center patients have indicated an interest in transferring to the proposed facility because it will reduce their travel time and/or be more convenient. In order to make the travel to dialysis three times a week more convenient for the in-center patients identified in Exhibit C.3, it was determined that BMA needs to provide another dialysis facility in the eastern part of Granville County. This could have a positive effect on their quality of life, and also on their ability and willingness to be more compliant with their treatment schedule.”*

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

- Exhibit C.3 documents the 40 in-center patients who are interested in transferring their care to the proposed facility, and that the new facility will be more convenient for them.

### **Projected Utilization**

In Section Q, Form C, page 87, the applicant provides projected utilization, as illustrated in the following table.

	IC Stations	IC Patients
The applicant begins with the 40 patients dialyzing on 10 stations at the facility as of 12/31/2027	13	40
The facility's Granville County patient census is projected forward a year to 12/31/2028 and is increased by the AACR of 0.09%. This is the census at the end of FY1.		$40 \times 1.009 = 40.4$
The facility's Granville County patient census is projected forward a year to 12/31/2029 and is increased by the AACR of 0.09%. This is the census at the end of FY2.		$40.4 \times 1.009 = 40.7$

Source: Form C, page 87

The following are the in-center patient projections for the proposed dialysis facility using Granville County's 0.9% Average Annual Change Rate (AACR) for the past five years, as reported in Table 9B of the Proposed 2025 SMFP, for the 40 in-center patients living in Granville County. The period of the growth begins January 1, 2028, and is calculated forward to December 31, 2029.

Projected patients for FY1 and FY2 are rounded to the nearest whole number. Based on the calculations above, by the end of FY1, FKC Butner Dialysis is projected to have:

- $40.4 \text{ patients} / 13 \text{ certified stations} = 3.11 \text{ patients} / \text{station}$
- $3.11 / 4 = .777$  or 77.7% utilization rate

By the end of FY2, FKC Butner Dialysis is projected to have:

- $40.7 \text{ patients} / 13 \text{ certified stations} = 3.13 \text{ patients} / \text{station}$

- $3.13 / 4 = .783$  or 78.3% utilization rate

The projected utilization of 3.11 patients per station per week at the end of FY1 exceeds the minimum standard of 2.8 in-center patients per station per week required by 10A NCAC 14C.2203(a).

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

- The applicant's beginning patient census is based on and supported by letters from patients currently receiving dialysis treatment at the applicant's existing dialysis facilities who have indicated an interest in transferring to the proposed FKC Butner Dialysis facility.
- The applicant's projected utilization in the first two years of operation is based on and supported by the 5-Year AACR for Granville County.

### **Access to Medically Underserved Groups**

In Section C, page 29, the applicant states,

*"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, handicap, age or any other grouping/category or basis for being an underserved person."*

The applicant states the proposed services will be made available to all residents in the service area without qualifications. The facility will serve patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability and socioeconomic groups of patients in need of dialysis. 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	30.7%
Racial and ethnic minorities	81.9%
Women	42.2%
Persons with disabilities	14.5%
Persons 65 and older	60.8%
Medicare beneficiaries	88.0%
Medicaid recipients	31.3%

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 applicant's history of providing service to all residents of the service area, including underserved groups, without regard for anything other than the need for dialysis services.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for 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 develop a new 13-station dialysis facility by relocating no more than six dialysis stations from FMC Dialysis Services of Oxford and no more than seven dialysis stations from FMC Dialysis Services of Neuse River.

In Section D, pages 35-42, the applicant explains why it believes the needs of the population presently utilizing the services to be relocated will be met following completion of the project.

In Section D, page 35, the applicant provides the following tables.

FMC Oxford	
County where the facility is located	Granville
1. Total number of existing, approved, and proposed dialysis stations as of the application deadline.	25
2. Number of existing dialysis stations to be reduced, relocated or eliminated in this proposal	6
3. Total # of dialysis stations upon project completion of this project and all other projects involving this facility.	19

Source: Section D, page 35

FMC Neuse River	
County where the facility is located	Granville
3. Total number of existing, approved, and proposed dialysis stations as of the application deadline.	27
4. Number of existing dialysis stations to be reduced, relocated or eliminated in this proposal	7
4. Total # of dialysis stations upon project completion of this project and all other projects involving this facility.	20

Source: Section D, page 35

### **FMC Neuse River**

In Section D, page 37, the applicant provides a table showing the projected utilization for FMC Neuse River through the first two project years, as summarized below.

	IC Stations	IC Patients
Begin with the Granville County patient population as of December 31, 2024.	27	67.0
Project the Granville County patient population forward one year to December 31, 2025.		$67.0 \times 1.009 = 67.6$
Add the 16 in-center patients from other counties. This is the projected ending census for Interim Year 1.		$67.6 + 16.0 = 83.6$
Project the Granville County patient population forward one year to December 31, 2026.		$67.6 \times 1.009 = 68.2$
Add the 16 in-center patients from other counties. This is the projected ending census for Interim Year 2.		$68.2 + 16.0 = 84.2$
Project the Granville County patient population forward one year to December 31, 2027.		$68.2 \times 1.009 = 68.8$
Subtract the 17 in-center patients projected to transfer to FKC Butner Dialysis upon Certification.	$27 - 7 = 20$	$68.8 - 17.0 = 51.8$
Add the 16 in-center patients from other counties. This is the projected ending census for Interim Year 3.	20	$51.8 + 16.0 = 67.8$

- Projections for patient utilization begin with the patient population at FMC Neuse River as of December 31, 2024, as reported by the applicant. There were 67 IC patients at the facility. Of these 67 patients, 51 lived in the service area, Granville County, and 16 lived outside of the service area.
- The applicant projected the growth of the Granville County patient population using the Granville 5-Year Average Annual Change Rate (5-Year AACR) of 0.9%, as published in the 2025 SMFP.
- The applicant states that the projections do not apply a growth rate to patients who live outside the service area.

Based on the calculations above, by the end of OY1 FMC Neuse River is projected to have:

- $67.8 \text{ patients} / 20 \text{ certified stations} = 3.39 \text{ patients} / \text{station}$
- $3.39 / 4 = .8478$  or 84.78% utilization rate

On page 38, the applicant states,

*“Table 9D: Dialysis Station Need Determination by Facility in the 2025 SMFP does indicate that FMC Neuse River is not eligible to apply for any additional dialysis stations pursuant to the facility need methodology in 2025. The applicant intends to apply for additional stations at FMC Neuse River as needs are identified in the SMFP.”*

### **FMC Oxford**

In Section D, page 38, the applicant provides a table showing the projected utilization of FMC Oxford through the first two project years, as summarized

<b>FMC Oxford</b>	<b>Stations</b>	<b>IC Patients</b>
Begin with the Granville County patient population as of December 31, 2024.	25	57.0
Project the Granville County patient population forward one year to December 31, 2025.		$57.0 \times 1.009 = 57.5$
Add the 21 in-center patients from other counties. This is the projected ending census for Interim Year 1.		$57.5 + 21.0 = 78.5$
Project the Granville County patient population forward one year to December 31, 2026.		$78.5 \times 1.009 = 79.2$
Add the 21 in-center patients from other counties. This is the projected ending census for Interim Year 2.		$79.2 + 21.0 = 100.2$
Project the Granville County patient population forward one year to December 31, 2027.		$100.2 \times 1.009 = 101.1$
Subtract the 23 in-center patients projected to transfer to FKC Butner Dialysis upon Certification.	$25 - 6 = 19$	$101.1 - 23.0 = 78.1$
Add the 21 in-center patients from other counties. This is the projected ending census for Interim Year 3.	19	$78.1 + 21.0 = 99.1$

- Projections for patient utilization begin with the patient population at FMC Oxford as of December 31, 2024, as reported by the applicant. There were 78 ICHD patients at the facility. Of these 78 patients, 57 lived in the service area, Granville County, and 21 lived outside of the service area.
- The applicant projected the growth of the Granville County patient population using the Granville 5-Year Average Annual Change Rate (5-Year AACR) of 0.9%, as published in the 2025 SMFP.
- The applicant states that the projections do not apply a growth rate to patients who live outside the service area.
- The applicant states that FMC Oxford is eligible to apply for 14 additional dialysis stations. The applicant intends to apply for six additional stations in July 2025 as identified in the 2025 SMFP to backfill the stations to be relocated to the new FKC Butner Dialysis facility.

Based on the calculations above, by the end of FY1 FMC Oxford is projected to have:

- $56.6 \text{ patients} / 19 \text{ certified stations} = 2.98 \text{ patients} / \text{station}$
- $2.98 / 4 = .7441$  or 74.4% utilization rate

### **Access to Medically Underserved Groups**



The applicant adequately demonstrates that the needs of medically underserved groups that will continue to use dialysis services at FMC Neuse River and FMC Oxford will be adequately met following completion of the project for the following reasons:

- The applicant states that the relocation of stations from FMC Neuse River and FMC Oxford will have no effect on the ability of low-income persons, racial and ethnic minorities, women, disabled persons, and other under-served groups and the elderly to obtain need health care.
- The applicant states that FMC Neuse River and FMC Oxford, by policy, will continue to make dialysis services available to all residents in its service area without qualifications.
- The applicant states that FMC Neuse River and FMC Oxford will continue to assist uninsured/underinsured patients with identifying and applying for financial assistance: therefore, services are available to all patients including low- income persons, racial and ethnic minorities, women, disabled persons, elderly and other underserved persons.

The applicant adequately demonstrates the needs of medically underserved groups will be adequately met following completion of the project based on applicant history of providing care to these groups.

### **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 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.

The applicant proposes to develop a new 13-station dialysis facility by relocating no more than six dialysis stations from FMC Dialysis Services of Oxford and no more than seven dialysis stations from FMC Dialysis Services of Neuse River.

In Section E, page 44, 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:

- The applicant could have elected not to develop FKC Butner Dialysis: The applicant chose to develop FKC Butner Dialysis as an effort to bring dialysis care and treatment closer to the patient's residence. The applicant states that the development of this facility in Butner would bring in-center dialysis closer to the patient residence location and ultimately shortens the patient commute to and from dialysis. Therefore, this was not the most effective alternative.
- The applicant could have elected to develop FKC Butner Dialysis with fewer than 13 in-center dialysis stations: The applicant states did not choose to develop fewer than 13 in-center dialysis stations primarily because of the number of patients living in the town of Butner. Developing fewer than 13 stations would not meet the need that the patients of the area. Therefore, this was not the most effective alternative.
- The applicant could have elected to include home therapies at the new location: The applicant did not include home therapies at the new location in an effort to contain capital costs of development. The applicant already operates a home training program at its FMC Neuse River dialysis facility in Granville County. This facility offers home training for peritoneal dialysis and home hemodialysis and states that adding home training at this location would be costly. Therefore, this was not the most 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 states that its proposal is the most effective alternative because a facility located in another area of Granville County would not address the need of the patients identified.
- 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 develop a new 13-station dialysis facility FKC Butner Dialysis, by relocating no more than seven dialysis stations from FMC Dialysis Services of Neuse River and no more than six dialysis stations from FMC Dialysis Services of Oxford.**
  - 3. Upon completion of the proposed project, the certificate holder shall take the necessary steps to decertify seven stations at FMC Dialysis Services of Neuse River for a total of no more than 20 in-center stations upon completion of the project.**
  - 4. Upon completion of the proposed project, the certificate holder shall take the necessary steps to decertify six stations at FMC Dialysis Services of Oxford for a total of no more than 19 in-center stations upon completion of the project.**
  - 5. 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 January 1, 2026.**
  - 6. 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.

The applicant proposes to develop a new 13-station dialysis facility by relocating no more than six dialysis stations from FMC Dialysis Services of Oxford and no more than seven dialysis stations from FMC Dialysis Services of Neuse River.

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

On Form F.1a in Section Q, the applicant projects the total capital cost of the project, as shown in the table below.

Construction Costs	\$1,863,084
Architect/Engineering Fees	\$166,926
Non-Medical Equipment	\$275,350
Furniture	\$119,801
Other: Generator	\$26,906
Other: Contingency	\$92,737
<b>Total</b>	<b>\$2,544,804</b>

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 based on the following:

- The applicant states that the capital costs for this project were developed by the Fresenius Real Estate and Construction Services team. Construction estimates are based upon a national database used by the RECS team.
- The applicant identifies the items that are included in each category.

In Section F, pages 47-48, the applicant projects that start-up costs will be \$161,116 and initial operating expenses will be \$866,675 for a total working capital of \$1,027,791. On pages 48-49, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the following:

- The applicant provided a breakdown of the start up costs which included purchasing inventory of consumable supplies as well as staff labor and training in the timeframe between the completion of leasehold improvements and certification.
- The initial operating expenses are calculated as six months of the first-year expenses.

### **Availability of Funds**

In Section F, page 46, the applicant states that the capital cost will be funded by accumulated reserves. Exhibit F-2 contains a letter dated January 15, 2025, from VP Corporate Tax North America of Fresenius Medical Care Holdings, Inc. committing \$2,544,804 for the capital cost and total working capital of the proposed project. In Exhibit F.3, the applicant provides the consolidated financials for Fresenius Medical Care Holdings, Inc., which shows that as

September 30, 2024, Fresenius Medical Care Holdings, Inc., had adequate cash and assets to finance the capital and working capital costs of the proposed project.

The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project based on the documentation in Exhibit F.2 and Exhibit F.3 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.

<b>FKC Butner Dialysis</b>	<b>CY2028</b>	<b>CY2029</b>
Total Treatments	<b>5,947</b>	<b>6,000</b>
Total Gross Revenues (Charges)	\$37,410,312	\$37,747,005
Total Net Revenue	\$1,964,620	\$1,982,301
Average Net Revenue per Treatment	\$330	\$330
Total Operating Expenses (Costs)	\$1,712,945	\$1,733,351
Average Operating Expense per Treatment	\$288	\$289
<b>Net Income</b>	<b>\$251,675</b>	<b>\$248,951</b>

The assumptions used by the applicant in preparation of the pro-forma financial statements are provided in Form F.2 and in Form 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 and working 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 develop a new 13-station dialysis facility by relocating no more than six dialysis stations from FMC Dialysis Services of Oxford and no more than seven dialysis stations from FMC Dialysis Services of Neuse River.

On page 113, the 2025 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 Granville County. Facilities may serve residents of counties not included in their service area.

According to Table 9A on page 123 of the 2025 SMFP, there are two existing or approved dialysis facilities in Granville County as shown in the following table:

Granville County			
Facility	Certified stations of 12/31/2023	# of IC Patients 12/31/2023	Utilization by% as of 12/31/2023
FMC Dialysis Services Neuse River	27	77	71.30%
FMC Dialysis Services of Oxford	25	90	90.00%

Source: Table 9A of the 2025 SMFP

In Section G, page 53, the applicant explains why it believes its proposal would not result in the necessary duplication of existing or approved dialysis services in Granville County. The applicant states:

*“BMA is the only dialysis provider of in-center dialysis services in Granville County. The applicant is not proposing to develop new dialysis stations by this proposal. The applicant is instead proposing to relocate existing certified dialysis stations within Granville County. These stations have been previously approved and do not duplicate services.”*

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 the number of certified dialysis stations in Granville County.
- The applicant adequately demonstrates that the proposed relocation of the existing certified dialysis stations is needed in Granville County.

### **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.

- (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 develop a new 13-station dialysis facility by relocating no more than six dialysis stations from FMC Dialysis Services of Oxford and no more than seven dialysis stations from FMC Dialysis Services of Neuse River.

On Form H in Section Q, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	1 <sup>st</sup> FFY	2 <sup>nd</sup> FFY
	CY2028	CY2029
Administrator	1.00	1.00
Registered Nurses (RNs)	2.00	2.00
Technicians (PCT)	2.50	2.50
Dietician	0.75	0.75
Social Worker	0.75	0.75
Maintenance	0.50	0.50
Administration /Business Office	1.00	1.00
FMC Director of Operations	0.12	0.12
FMC Chief Technician	0.12	0.12
FMC In-Service	0.11	0.11
<b>Total</b>	<b>8.85</b>	<b>8.85</b>

Source: Section Q, Form H, page 107

The assumptions and methodology used to project staffing are provided 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 55-56,

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 methods it uses to attract qualified staff which enable the facility to maintain staffing levels.
- 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 develop a new 13-station dialysis facility by relocating no more than six dialysis stations from FMC Dialysis Services of Oxford and no more than seven dialysis stations from FMC Dialysis Services of Neuse River.

### **Ancillary and Support Services**

In Section I, page 57, the applicant identifies the necessary ancillary and support services for the proposed services. In Section I, pages 57-61, 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 62, 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 because the



applicant has existing relationships with local health care and social service providers 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.

- (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.

- (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

- (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.

### C

The applicant proposes to develop a new 13-station dialysis facility by relocating no more than six dialysis stations from FMC Dialysis Services of Oxford and no more than seven dialysis stations from FMC Dialysis Services of Neuse River.

In Section K, page 65, the applicant states that the project involves renovating approximately 6,000 square feet of existing space. Line drawings are provided in Exhibit K-2.

In Section K, pages 65-67, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following:

- The applicant states that the proposed site is an existing shell space that will be upfitted to accommodate the provision of dialysis services, including 13 stations and office space for support staff. (Exhibit K-2)
- The applicant states its parent company has extensive experience designing dialysis facilities and incorporating cost-saving measures. (page 65)

In Section K, page 66, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the following:

- The applicant states the costs of the proposed project are the responsibility of the applicant and the costs are not passed on to patients.
- The applicant states the project will not increase costs or charges to the public for the proposed services.

In Section K, pages 65-67, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit K.4.

### **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.

- (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 70, the applicant provides the historical payor mix during CY2023 for its existing services at FMC Neuse River and FMC Oxford, as shown in the table below.

Payor Source	FMC Neuse River					
	In-center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-Pay	1.0	1.25%	0.0		0.0	
Insurance*	2.5	3.19%	0.0		0.0	1.44%
Medicare*	64.4	83.61%	1.0	100.00%	1.7	87.16%
Medicaid*	2.7	3.54%	0.0		0.0	1.21%
Other-VA	6.5	8.41%	0.0		0.2	10.19%
<b>Total</b>	<b>77.0</b>	<b>100.00%</b>	<b>1.0</b>	<b>100.00%</b>	<b>2.0</b>	<b>100.00%</b>

Payor Source	FMC Oxford					
	In-center Dialysis		Home Hemodialysis **		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-Pay	1.6	2.10%				
Insurance*	5.5	7.02%				
Medicare*	62.9	80.61%				
Medicaid*	5.7	7.27%				
Other-VA	2.3	3.01%				
<b>Total</b>	<b>78.0</b>	<b>100.00%</b>				

In Section L, page 71 the applicant provides the following comparisons.

FMC Neuse River	Last Full FY before Submission of the Application	
	Percentage of Total Patients*	Percentage of the Population of the Service Area^
Female	38.6%	48.6%
Male	67.4%	51.4%
Unknown	0.0%	0.0%
64 and Younger	33.0%	81.6%
65 and Older	67.0%	18.4%
American Indian	0.0%	1.1%
Asian	0.0%	0.9%
Black or African American	83.0%	31.0%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	17.0%	64.6%
Other Race	0.0%	13.7%
Declined/ Unavailable	0.0%	0.0%

\* All patients (in-center, home hemodialysis, and peritoneal dialysis).

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

FMC Oxford	Last Full FY before Submission of the Application	
	Percentage of Total Patients Served	Percentage of the Population of the Service Area^
Female	46.2%	48.6%
Male	53.8%	51.4%
Unknown	0.0%	0.0%
64 and Younger	46.2%	81.6%
65 and Older	53.8%	18.4%
American Indian	0.0%	1.1%
Asian	2.6%	0.9%
Black or African American	75.6%	31.0%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	19.2%	64.6%
Other Race	2.6%	13.7%
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>. Just enter in the name of the county.

### **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 71, the applicant states it has no such obligation.

In Section L, page 72, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights equal access complaints have been filed against FMC Neuse River or FMC Oxford.

### **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, pages 72, 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.

FKC Butner Dialysis Projected Payor Mix CY2029		
Payment Source	IC	
	# Patients	% Patients
Self-Pay	0.7	1.68%
Insurance*	2.1	5.11%
Medicare*	33.4	82.11%
Medicaid*	2.2	5.41%
Other	2.3	5.71%
<b>Total</b>	<b>40.7</b>	<b>100.00%</b>

\*Including any managed care plans  
Source: Section L, page 72

As shown in the table above, during the second full fiscal year of operation, the applicant projects 1.68% of services will be provided to self-pay patients, 82.11% of services will be provided to Medicare patients; and 5.41% of services will be provided to Medicaid patients.

On page 72, 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 experience of the two existing dialysis facilities.

### **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 74, the applicant adequately describes the range of means by which patients will have access to the proposed services and provides supporting documentation in Exhibit L-4.

### **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 develop a new 13-station dialysis facility by relocating no more than six dialysis stations from FMC Dialysis Services of Oxford and no more than seven dialysis stations from FMC Dialysis Services of Neuse River.

In Section M, page 75, 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 applicant provides a copy of a letter sent to Vance Granville Community College offering the facility as a training site for nursing students.

**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 develop a new 13-station dialysis facility by relocating no more than six dialysis stations from FMC Dialysis Services of Oxford and no more than seven dialysis stations from FMC Dialysis Services of Neuse River.

On page 113, the 2025 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 Granville County. Facilities may serve residents of counties not included in their service area.

According to Table 9A on page 123 of the 2025 SMFP, there are two existing or approved dialysis facilities in Granville County as shown in the following table:

Granville County			
Facility	Certified stations of 12/31/2023	# of IC Patients 12/31/2023	Utilization by% as of 12/31/2023
FMC Dialysis Services Neuse River	27	77	71.30%
FMC Dialysis Services of Oxford	25	90	90.00%

Source: Table 9A of the 2025 SMFP

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 76, the applicant states:

*“The applicant does not expect this proposal to have any effect on the competitive climate in Granville County. The applicant does not project to serve dialysis patients currently being served by another provider. The projected patient population for the facility begins with the current patient population, projected patient transfers, and growth of that population consistent with the Granville County Five Year Average Annual Change Rate published in the 2025 SMFP.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 77, the applicant states:

*“This is a proposal to relocate 13 existing in-center dialysis stations to develop a new facility in Creedmoor in Granville County. 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 of the area in a convenient setting. As a result, 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, K, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 77, 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 B and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 77, the applicant states:

*“Fresenius related facilities in North Carolina have historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for being an underserved person. Low income and medically underinsured persons will continue to have access to all services provided by Fresenius- related facilities.”*

See also Section 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:

- 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.
- 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.
- 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

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 develop a new 13-station dialysis facility by relocating no more than six dialysis stations from FMC Dialysis Services of Oxford and no more than seven dialysis stations from FMC Dialysis Services of Neuse River.

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 132 existing or approved kidney disease treatment facilities located in North Carolina.

In Section O, page 82, 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 the information provided by the applicant and publicly available data considering the quality of care provided at all 132 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.

**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.*

- C- In Section C.3, page 25, the applicant projects 40.4 in-center patients will be served by the proposed facility by the end of the first operating year, FY 2028 for utilization rate of 3.11 patients per station per week or 77.75% ( $40.4 \text{ patients} / 13 \text{ stations} = 3.11 \text{ patients per station} / 4 = 0.7775$ ) The projected utilization of 3.11 patients per station per week exceeds the 2.8 in-center patients per station threshold required by this rule.
- (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.*
- NA- The applicant is proposing to establish a new ESRD facility.
- (c) *An applicant shall provide all assumptions; including the methodology by which patient utilization is projected. 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 does not propose to establish a new dialysis facility dedicated to home hemodialysis or peritoneal dialysis. Therefore, this Rule does not apply.
- (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) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section C, pages 24-25, and 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.