

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: May 10, 2024

Findings Date: May 10, 2024

Project Analyst: Chalice L. Moore

Co-Signer: Michael McKillip

Project ID #: O-12500-24

Facility: Fresenius Medical Care of Brunswick County

FID #: 070678

County: Brunswick

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

Project: Add no more than one dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 11 stations upon project completion

### REVIEW CRITERIA

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

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

### C

Bio-Medical Applications of North Carolina, Inc. (hereinafter referred to as “BMA” or “the applicant”) proposes to add no more than one dialysis station to Fresenius Medical Care of Brunswick County (FMC Brunswick) pursuant to Condition 2 of the facility need methodology for a total of no more than 11 dialysis stations upon project completion.

#### **Need Determination (Condition 2)**

Chapter 9 of the 2024 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 9B, the county need methodology shows there is no county need determination for additional dialysis stations in Brunswick County.

However, the applicant is eligible to apply for additional dialysis stations in an existing facility pursuant to Condition 2 of the facility need methodology in the 2024 SMFP, if the utilization rate for the facility as reported in the 2024 SMFP is at least 75 percent or 3.0 patients per station per week, as stated in Condition 2.a. The utilization rate reported for the facility is 90% or 3 patients per station per week, based 36 in-center dialysis patients and 10 certified dialysis stations (36 patients /10 stations = 3.6, 3.6 / 4 = 90%).

The applicant proposes to add no more than one dialysis station to the facility, which is consistent with the 2024 SMFP calculated facility need determination for up to 11 stations; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

### **Policies**

There is one policy in the 2024 SMFP, Policy GEN-3:

*“Basic Principles A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”*

### **Promote Safety and Quality**

The applicant describes how the proposed project will promote safety and quality in Section B, pages 21 and 23; Section N, pages 75-76; Section O, pages 78-80; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote safety and quality.

### **Promote Equitable Access**

The applicant describes how the proposed project will promote equitable access in Section B, pages 22-23; Section C, pages 33-34; Section L, pages 67-73; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote equitable access.

### **Maximize Healthcare Value**

The applicant describes how the proposed project will maximize healthcare value in Section B, pages 22-23; Section N, page 76; Section O, pages 78-80; and referenced exhibits. The

information provided by the applicant is reasonable and supports the determination that the applicant's proposal will maximize healthcare value.

### **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 the following:

- The applicant adequately demonstrates that the application is consistent with the facility need methodology as applied from the 2024 SMFP.
  - The applicant adequately demonstrates that the application is consistent with Policy GEN-3 based on the projects proposed incorporation of safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended.
- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

### **C**

FMC Brunswick proposes to add no more than one dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 11 stations upon project completion.

### **Patient Origin**

On page 113, the 2024 SMFP defines the service area for dialysis stations as "*the county in which the dialysis station is located*". Thus, the service area for this facility consists of Brunswick County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates historical and projected patient origin.

FMC Brunswick Current & Projected Patient Origin												
	Historical – CY 2023						Projected – CY 2027					
	IC Patients		HH Patients		PD Patients		IC Patients		HH Patients		PD Patients	
	#	%	#	%	#	%	#	%	#	%	#	%
Brunswick	27.0	79.4%	1.0	50.0%	0	0.0%	32.6	94.2%	1.2	54.7%		
Beaufort	0.0	0%	0.0	0%	1.0	100%	0.0	0%	0.0	0%	1.0	100.0%
Columbus	1.0	2.9%	0.0	0%	0.0	0%	1.0	2.9%	0.0	0%	0.0	0%
Johnson	1.0	2.9%	0.0	0%	0.0	0%	0.0	0%	0.0	0%	0.0	0%
Randolph	1.0	2.9%	0.0	0%	0.0	0%	0.0	0%	0.0	0%	0.0	0%
Rockingham	1.0	2.9%	0.0	0%	0.0	0%	0.0	0%	0.0	0%	0.0	0%
Sampson	0.0	0%	1.0	50.0%	0.0	0%	0.0	0%	1.0	45.3%	0.0	0%
South Carolina	1.0	2.9%	0.0	0%	0.0	0%	1.0	2.9%	0.0	0%	0.0	0%
Tennessee	1.0	2.9%	0.0	0%	0.0	0%	0.0	0%	0.0	0%	0.0	0%
Other States	1.0	2.9%	0.0	0%	0.0	0%	0.0	0%	0.0	0%	0.0	0%
<b>Total</b>	<b>34.0</b>	<b>100%</b>	<b>2.0</b>	<b>100.0%</b>	<b>1.0</b>	<b>100.0%</b>	<b>34.6</b>	<b>100.0%</b>	<b>2.2</b>	<b>100.0%</b>	<b>1.0</b>	<b>100.0%</b>

Source Section C, pages 25-26

The facility currently offers and will continue to offer home hemodialysis and peritoneal dialysis training and support services upon project completion.

In Section C, pages 25-26, and the Form C Utilization subsection of Section Q page 84, 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 historical (CY2023) patient origin for the facility.

**Analysis of Need**

In Section C, pages 29-30, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

*“The need that this population has for the proposed services is a function of the individual patient’s 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 33.1 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 75.2%, or 3.01 patients per station and exceeds the minimum required by the performance standard.”*

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

- The applicant demonstrates eligibility to add dialysis stations to its facility under Condition 2 of the facility need methodology, as stated in the 2024 SMFP. The discussion regarding need methodology found in Criterion (1) is incorporated herein by reference.

- The applicant adequately demonstrates need based on the facility’s projected growth in the patient population.

Projected Utilization

*In-Center Utilization*

In Section C, pages 27-28, and in Form Utilization C Section Q, pages 83-84, the applicant provides the in-center projected utilization for FMC of Brunswick, as illustrated in the following table.

<b>FMC Brunswick</b>	<b>In-Center patients</b>
Begin with the Brunswick County patient population as of December 31, 2023.	27.0
Project the Brunswick County patient population forward 1 year to December 31, 2024, using the Brunswick County 5-Year AACR	$27.0 \times 1.048 = 28.3$
Add the patient from other counties and South Carolina. This is the projected ending census for Interim Year 1.	$28.3 + 2.0 = 30.3$
Project the Brunswick County patient population forward to December 31, 2025, using the Brunswick County 5-Year AACR	$28.3 \times 1.048 = 29.7$
Add the patient from other counties and South Carolin. This is the projected ending census for Interim Year 2.	$29.7 + 2.0 = 31.7$
Project the Brunswick County patient population forward to December 31, 2026, using the Brunswick County 5-Year AACR	$29.7 \times 1.048 = 31.1$
Add the patient from other counties and South Carolina. <b>This is the projected ending census Operating Year 1.</b>	$31.1 + 2.0 = 33.1$
Project the Brunswick County patient population forward for one year to December 31, 2027, using the Brunswick County 5-Year AACR.	$31.1 \times 1.048 = 32.6$
Add the patient from other counties and South Carolina. <b>This is the projected ending census for Operating Year 2.</b>	$32.6 + 2.0 = 34.6$

Source: Section C, pages 27-28

In Section C, pages 28-29, and in the Form C Utilization subsection of Section Q page 86, the applicant provides the assumptions and methodology used to project patient utilization, which are summarized below.

- The applicant begins its utilization projections with the patient census on December 31, 2023. The applicant states that on December 31, 2023, its in-center patient census was comprised of 27 Brunswick County patients.
- The applicant projects growth of the Brunswick County Patient population using the Brunswick Five Year Average Annual Change Rate (5-Year AACR) of 4.8%, as published in the 2024 SMFP.

- As of December 31, 2023, the facility was serving two home hemodialysis patients residing in Brunswick and Sampson Counties and one peritoneal dialysis patient residing in Beaufort County. While Sampson County and Beaufort County are not contiguous to Brunswick County; home dialysis patients do not travel three days a week for treatment as in-center patients once their training is completed, thus, the applicant states it is reasonable that patients residing in these areas would continue dialysis at FMC Brunswick as a function of patient choice.
- All dialysis patients from other counties are assumed to continue dialysis with the facility; however, the applicant does not project any growth for this segment of the patient population. The patients will be added to projections of future patient populations at appropriate points in time.
- The new station is projected to be certified as of December 31, 2025, therefore Operating Year 1 is the period from January 1- December 31, 2026, and Operating Year 2 is the period from January 1- December 31, 2027.

*Home Hemodialysis and Peritoneal Dialysis Methodology:*

In Section C, page 28, the applicant provides the projected utilization for FMC Brunswick, as shown in the following table:

Brunswick County	Home Hemodialysis	Peritoneal Dialysis
Begin with the Brunswick County patient population as of December 31, 2023.	1.0	
Project the Brunswick County patient population forward one year to December 31, 2024, using the Brunswick County 5-Year AACR	$1.0 \times 1.048 = 1.0$	
Add the patient from other counties. This is the projected ending census for Interim Year 1.	$1.0 + 1.0 = 2.0$	1.0
Project the Brunswick County patient population forward for one year to December 31, 2025, using the Brunswick County 5-Year AACR	$1.0 \times 1.048 = 1.1$	
Add the patient from other counties. This is the projected ending census for Interim Year 2.	$1.1 + 1.0 = 2.1$	1.0
Project the Brunswick County patient population forward for one year to December 31, 2026, using the Brunswick County 5-Year AACR	$1.0 \times 1.048 = 1.2$	
Add the patient from other counties. <b>This is the projected ending census Operating Year 1.</b>	$1.2 + 1.0 = 2.2$	1.0
Project the Brunswick County patient population forward for one year to December 31, 2027, using the Brunswick County 5-Year AACR.	$1.2 \times 1.048 = 1.2$	
Add the patient from other counties. <b>This is the projected ending census for Interim Year 2.</b>	$1.2 + 1.0 = 2.0 = 2.2$	1.0

Source Section C, pages 26-27

Based on these calculations, BMA projects to serve the following number of patients for the Operating Years 1 & 2.

	Operating Year 1	Operating Year 2
In-Center Dialysis	33.1	34.6
Home Hemodialysis	2.2	2.2
Peritoneal Dialysis	1.0	1.0

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

- The applicant bases the projections of the future patient population to be served at the facility based on actual patient census as of December 31, 2023.
- The applicant projects growth of the Brunswick County patient population using the Brunswick County Five Year Average Annual Change Rate (5-Year AACR) of 4.8%, as published.

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

In Section C, page 33, the applicant states:

*“Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.*

*It is our corporate policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, or health insurer.*

*Fresenius Medical Care and its related facilities in North Carolina have historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for being an underserved person.”*

In Section C, pages 33-34, the applicant provides the estimated percentage of total patients to be served for each medically underserved group, as shown in the following table.

<b>Medically Underserved Groups</b>	<b>Percentage of Total Patients</b>
Low-income persons	28.1%
Racial and ethnic minorities	43.8%
Women	46.9%
Persons with Disabilities	9.4%
The elderly	62.5%
Medicare beneficiaries	37.5%
Medicaid recipients	12.5%

Source: Section C, page 33-34

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 services to medically underserved 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 all the reasons described above.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

### NA

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

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

### C

FMC Brunswick proposes to add no more than one dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 11 stations upon project.

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 were considered:

- Maintain the status quo The applicant could have chosen not to file for additional stations at FMC Brunswick County. Failure to apply for additional stations at FMC Brunswick County would ultimately result in higher utilization rates. The applicant has demonstrated that the projected utilization for the end of Operating Year 1 is 3.01 patients per station; the projected utilization for the end of Operating Year 2 is 3.14 patients per station. If FMC Brunswick County had chosen to not apply for additional stations, utilization on 10 dialysis stations would be projected to be 3.31 patients per station at the end of Operating Year 1, and 3.46 patients per year at the end of Operating Year 2. Failure to apply for additional stations, utilization rates, potentially interrupts patient admissions to the facility and is the least effective alternative.
- Apply for as many as 11 stations. An application for more than one station is not cost effective. The facility does not have the physical space for more than one dialysis station, even though the facility qualifies to apply for as many as 11 stations.

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

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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 Facilities of North Carolina, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
  - 2. Pursuant to Condition 2 of the facility need determination in the 2024 SMFP, the certificate holder shall develop no more than one additional dialysis station for a total of no more than 11 stations at the FMC Brunswick upon completion of this project.**
  - 3. Progress Reports:**
    - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
    - b. The certificate holder shall complete all sections of the Progress Report form.**
    - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
    - d. The first progress report shall be due October 1, 2024.**
  - 4. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

FMC Brunswick proposes to add no more than one dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 11 stations upon project completion.

**Capital and Working Capital Cost**

In Section F, page 46, the applicant projects a capital cost of \$3,750. The assumptions used to project capital cost in Form F. 1a Capital Cost are provided in Section Q, pages 90-91.

In Section F, page 46, the applicant states there are no projected capital or working capital costs because it is an existing facility that is already operational.

**Availability of Funds**

In Section F, page 44, the applicant projects the capital cost of the project, as shown in the table below.

<b>Source of Financing for Working Capital</b>	<b>Amount</b>
Loans	\$0
Accumulated Reserves or OE*	\$3750
Bonds	\$0
Other (Describe)	\$0
<b>Total Financing</b>	<b>\$3750</b>

\*OE= Owner’s Equity **Source:** Section F, page 44

The applicant is relying upon the corporate accumulated reserves of Fresenius Medical Care Holdings, Inc. to finance this project. Exhibit F-2 is a letter of commitment from the VP of Corporate Tax for Fresenius Medical Care Holdings, Inc. This letter will verify the availability of the funds necessary for the project.

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

**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, in Section Q, the applicant projects that operating expenses will exceed revenues in the first two full fiscal years following completion of the project, as shown in the table below:

	<b>1<sup>st</sup> Full FY CY 2026</b>	<b>2<sup>nd</sup> Full FY CY 2027</b>
Total Treatment	5,253	5,476
Total Gross Revenues (Charges)	\$33,044,136	\$34,451,490
Total Net Revenue	\$1,959,383	\$2,034,189
Average Net Revenue per Treatment	\$373	\$371
Total Operating Expenses (Costs)	\$1,755,626	\$1,796,827
Average Operating Expense per Treatment	\$334	\$328
Net Income	\$203,758	\$237,362

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

- The applicant adequately explains the assumptions used to project revenue, such as projected reimbursement rates, and operating costs, such as salaries.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
  - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
- (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

FMC Brunswick proposes to add no more than one dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 11 stations upon project completion.

On page 113, the 2024 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 Brunswick County. Facilities may serve residents of counties not included in their service area.

According to Table 9A, page 119 of the 2024 SMFP, there are four existing dialysis facilities in Brunswick County, as shown in the following table:

<b>Dialysis Facility</b>	<b>Certified Stations 12/31/2022</b>	<b>In-Center Patients 12/31/2022</b>	<b>Utilization</b>
FMC Brunswick County	20	36	90.00%
Leland Dialysis	16	60	93.75%
Southport Dialysis Center Shallotte	15	39	65.00%
Southport Dialysis Center	11	36	81.82%

In section G, page 51, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Brunswick County. The applicant states:

*“This application is to add one dialysis station to an existing dialysis facility based upon the performance and demonstrated need at the FMC Brunswick facility. The need addressed by this application is not specific to Brunswick County as a whole. The station is needed by the patient population projected to be served at the facility”.*

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

- The applicant proposes to increase the number of dialysis stations at FMC Brunswick County based on Condition 2 of the facility need determination in the 2024 SMFP.
- The applicant adequately demonstrates that the proposed dialysis station is needed in addition to the existing or approved dialysis stations in Brunswick County.

### **Conclusion**

The Agency reviewed the:

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

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

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

FMC Brunswick proposes to add one dialysis station to the existing facility pursuant to Condition 2 of the facility need methodology for a total of no more than 11 stations upon project completion.

In Section Q, Form H, pages 101-102, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Current FTE Staff	Projected FTE Staff	Projected FTE Staff
	As of 2/6/2024	Year 1 2026	Year 2 2027
Administrator (FMC Clinic Manager)	1.00	1.00	1.00
Registered Nurses (RNs)	1.50	2.50	2.50
Home Training Nurse	1.00	1.00	1.00
Technicians (PCT)	3.00	4.00	4.00
Medical Records	0.50	0.50	0.50
Dietician	0.50	0.50	0.50
Social Worker	0.50	0.50	0.50
Maintenance	0.50	0.50	0.50
Administration/Clerical	0.50	0.50	0.50
Other (FMC Director of Operations)	0.10	0.10	0.10
Other (FMC Chief Technician)	0.10	0.10	0.10
Other (FMC in-Service)	0.10	0.10	0.10
<b>Total</b>	<b>9.30</b>	<b>11.30</b>	<b>11.30</b>

Source: Section Q, Form H pages, 101-102

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 Form F.4. In Section H, pages 53-54, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

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

- The facility is an existing facility, and the applicant bases its staffing on its historical experience providing dialysis services at the facility.
- The applicant has existing policies regarding recruitment, qualifications for staff, training, and continuing education.

**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

FMC Brunswick proposes to add one dialysis station to the existing facility pursuant to Condition 2 of the facility need methodology for a total of no more than 11 stations upon project completion.

**Ancillary and Support Services**

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

**Coordination**

In Section I, page 60, 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 its established relationships with other physicians and hospitals in the area and its agreements 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.

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

NA

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

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

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

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and ... persons [with disabilities], which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C



In Section L, page 67, the applicant provides the historical payor mix for CY2023 as shown in the table below.

<b>FMC Brunswick</b>						
<b>Payment Source</b>	<b>In-Center</b>		<b>Home Hemodialysis</b>		<b>Peritoneal Dialysis</b>	
	<b># Patients</b>	<b>% Patients</b>	<b># Patients</b>	<b>% Patients</b>	<b># Patients</b>	<b>% Patients</b>
Self-Pay	1.5	4.47%	0.0	0.0%	0.0	0.0%
Insurance*	2.1	5.98%	1.3	59.9%	1.0	100.0%
Medicare*	28.8	83.40%	0.5	23.3%	0.0	0.0%
Medicaid*	2.1	6.07%	0.0	0.0%	0.0	
Other misc. including VA	0	0.09%	0.4	16.8%	0.0	0.0%
<b>Total</b>	<b>34.6</b>	<b>100.00%</b>	<b>2.2</b>	<b>100.00%</b>	<b>1.0</b>	<b>100.0%</b>

In Section L, page 69, the applicant provides the following population comparison of the service area.

<b>FMC Brunswick</b>	<b>Percentage of Total Patients Served (All modalities combined)</b>	<b>Percentage of the Population of the Service Area where the Stations will be Located or Services Offered*</b>
Female	46.9%	51.9%
Male	53.1%	48.1%
Unknown		
64 and Younger	37.5%	66.0%
65 and Older	62.5%	34.0%
American Indian	3.1%	0.8%
Asian		0.8%
Black or African-American	28.1%	9.3%
Native Hawaiian or Pacific Islander		0.1%
White or Caucasian	65.6%	87.0%
Other Race	3.1%	7.2%
Declined / Unavailable		

Sources: BMA Internal Data, US Census Bureau

**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 67, the applicant states it has no such obligation.

In Section L, pages 69-70, the applicant states that during the 18 months immediately preceding the application deadline no patient civil rights access complaints have been filed against FMC Brunswick.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section L, page 70, 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.

<b>FMC Brunswick Projected Payor Mix CY2027</b>						
	<b>In-Center</b>		<b>HH</b>		<b>PD</b>	
<b>Payment Source</b>	<b># Patients</b>	<b>% Patients</b>	<b># Patients</b>	<b>% Patients</b>	<b># Patients</b>	<b>% Patients</b>
Self-Pay	1.5	4.47%	0.0	0.0	0.0	
Insurance*	2.1	5.98%	1.3	59.9%	1.0	100.0%
Medicare*	28.8	83.40%	0.5	23.3%	0.0	
Medicaid*	2.1	6.07%	0.0	0.0%	0.0	
Other (VA)	0.0	0.09%	0.4	16.8%	0.0	
<b>Total</b>	<b>34.6</b>	<b>100.00%</b>	<b>2.2</b>	<b>100.00%</b>	<b>1.0</b>	<b>100.0%</b>

\*Including any managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 4.47 percent of in-center services will be self-pay; 83.40 percent of in-center services will be covered by Medicare, and 6.07 percent of in-center services will be covered by Medicaid.

On pages 70-71, the applicant provides the assumptions and methodology it uses to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical payor mix at FMC Brunswick.

**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 72, the applicant adequately describes the range of means by which patients will have access to the proposed services.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

FMC Brunswick proposes to add one dialysis station to the existing facility pursuant to Condition 2 of the facility need methodology for a total of no more than 11 stations upon completion of this project.

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

- The applicant provides a copy of a letter sent to Cape Fear Community College offering the facility as a training site for nursing students.
- The applicant states it intends to serve as a host for health-related education and 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.

- (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

FMC Brunswick proposes to add one dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 11 stations upon completion of this project.

On page 113, the 2024 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 Brunswick County. Facilities may serve residents of counties not included in their service area.

According to Table 9A on page 119 of the 2024 SMFP, there are four existing facilities which provide dialysis services in Brunswick County. Information on all four of these dialysis facilities is provided in the table below.

Facility Name	Certified Stations as of 12/31/2022	Patients as of 12/31/2022	Utilization by Percent as of 12/31/2022
FMC Brunswick County	10	36	90.00%
Leland Dialysis	16	60	93.75%
Southeastern Dialysis Center- Shallotte	15	39	65.00%
Southport Dialysis	11	36	81.82%

Source: Table 9A, Chapter 9, 2024 SMFP, page 119

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 75, the applicant states:

*“The applicant does not expect this proposal to have any effect on the competitive climate in Brunswick County. The applicant does not project to serve dialysis patients currently being served by another provider.”*

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

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

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

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

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

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 76, the applicant states:

*“All Fresenius Medical Care related facilities in North Carolina have a history of providing dialysis services to the underserved populations of North Carolina. .... Each of those facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, [people with disabilities], 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 any other factor that would classify a patient as underserved.*

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

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

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

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

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

- Information which was publicly available during the review and used by the Agency

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

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

FMC Brunswick proposes to add one dialysis station to the existing facility pursuant to Condition 2 of the facility need methodology for a total of no more than 11 stations upon completion of this project.

On Form O, pages 104-108, 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 81, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents resulting in an Immediate Jeopardy violation that occurred in any of these facilities. After reviewing and considering information provided by the applicant and 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.

**10 CAC 14C .2203 PERFORMANCE STANDARDS**

- (a) An applicant proposing to establish a new kidney disease treatment center or dialysis facility shall document the need for at least 10 dialysis stations based on utilization of 2.8*

*in-center patients per station per week as of the end of the first 12 months of operation following certification of the facility. An applicant may document the need for less than 10 stations if the application is submitted in response to an adjusted need determination in the State Medical Facilities Plan for less than 10 stations.*

- NA- FMC Brunswick is an existing facility. Therefore, this Rule is not applicable to this review.
    - (b) *An applicant proposing to increase the number of dialysis stations in:*
      - (1) *an existing dialysis facility; or*
      - (2) *a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need; shall document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the additional stations.*
- 
- C- In Section C, page 26, and on Form C in Section Q, the applicant projects to serve 33.1 patients on 11 stations, or a rate of 3.01 in-center patients per station per week (36.2 patients / 11 stations = 3.01), by 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 does not propose to establish a new dialysis facility dedicated to home hemodialysis or peritoneal dialysis training. 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 does not propose to increase the number of home hemodialysis stations. Therefore, this Rule does not apply.
  - (e) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- 
- C- In Section C, pages 26-28, and in the Form C Utilization subsection of 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.