

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: October 4, 2022

Findings Date: October 4, 2022

Project Analyst: Donna Donihi

Co-Signer: Mike McKillip

Project ID #: K-12242-22

Facility: FMC Dialysis Services Neuse River

FID #: 170422

County: Granville

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

Project: Add no more than two dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 27 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

The applicant, Bio-Medical Applications of North Carolina, Inc. (FMC Neuse River), proposes to add no more than two dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 27 stations upon project completion.

#### **Need Determination**

Chapter 9 of the 2022 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table 9B, page 136, the county need methodology shows there is not a county need determination for additional dialysis stations in Granville County.

However, the applicant is eligible to apply for additional dialysis stations in an existing facility pursuant to Condition 2 of the facility need methodology in the 2022 SMFP, if the utilization rate for the facility as reported in the 2022 SMFP is at least 75.00% or 3.0 patients per station per week, as stated in Condition 2.a. In Table 9A, page 125, the utilization rate reported for the facility is 77% or 3.08 patients per station per week, based on 77 in-center dialysis patients and 25 certified dialysis stations (77 patients / 25 stations = 3.08;  $3.08 / 4 = 0.77$ ).

As shown in Table 9D, page 140, based on the facility need methodology for dialysis stations, the potential number of stations needed is up to 5 additional stations; thus, the applicant is eligible to apply to add up to 5 stations during the 2022 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than two new stations to the facility pursuant to Condition 2 in the 2022 SMFP review cycle, which is consistent with the 2022 SMFP calculated facility need determination for up to 5 stations; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

### **Policies**

There is one policy in the 2022 SMFP which is applicable to this review. *Policy GEN-3: Basic Principles*, on page 30 of the 2022 SMFP, states:

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

### **Promote Safety and Quality**

The applicant describes how it believes the proposed project will promote safety and quality in Section B, page 21; Section N, page 75; Section O, pages 77-80; 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 it believes the proposed project will promote equitable access in Section B, page 22; Section C, page 32; Section L, pages 67-72; Section N, page 75; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote equitable access.

### Maximize Healthcare Value

The applicant describes how it believes the proposed project will maximize healthcare value in Section B, pages 22-23; Section N, page 75; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant's proposal will maximize healthcare value.

The applicant adequately demonstrates how its proposal incorporates the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need as identified by the applicant. Therefore, the application is consistent with Policy GEN-3.

### Conclusion

The Agency reviewed the:

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

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

- The applicant adequately demonstrates that the application is consistent with the facility need methodology as applied from the 2022 SMFP.
- The applicant adequately demonstrates how the facility's projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need.
- The applicant adequately demonstrates that the application is consistent with Policy GEN-3 based on how it describes the facility's policies and programs, which promote the concepts of quality, equitable access and maximum value for resources.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

### C

The applicant proposes to add no more than two dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 27 stations upon project completion.

**Patient Origin**

On page 115, the 2022 SMFP defines the service area for the county need methodology 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.” FMC Neuse River is located in Granville County. Thus, the service area for this application is Granville County. Facilities may serve residents of counties not included in their service area.

In Section C.2, page 25, the applicant provides the historical in-center (IC) and peritoneal dialysis (PD) patient origin for FMC Neuse River, as summarized below. The facility does not serve home hemodialysis (HH) patients.

**Historical Patient Origin  
 (1/1/2021-12/31/2021)**

County	Patients	% of Total	# of Peritoneal Dialysis Patients	% of total
Granville	59.0	79.7%	3.0	100.0%
Vance	12.0	16.2%	0.0	0.0
Warren	2.0	2.7%	0.0	0.0
Virginia	1.0	1.4%	0.0	0.0
<b>Total</b>	<b>75.9</b>	<b>100.0%</b>	<b>3.0</b>	<b>100%</b>

The following table summarizes the projected in-center patient origin at FMC Neuse River in the second full fiscal year (FY) of operations, calendar year (CY) 2025, as provided on page 26 of the application.

**Second Full FY of Operation following Project Completion  
 CY2025**

County	Patients	% of Total	# of Peritoneal Dialysis Patients	% of total
Granville	58.9	77.6%	6.0	100%
Durham	2.0	2.6%	N/A	N/A
Franklin	1.0	1.3%	N/A	N/A
Vance	12.0	15.8%	N/A	N/A
Wake	1.0	1.3%	N/A	N/A
Warren	1.0	1.3%	N/A	N/A
<b>Total</b>	<b>75.9</b>	<b>100.0%</b>	<b>6.0</b>	<b>100%</b>

In Section C, pages 26-27, the applicant provides the assumptions and methodology used to project its patient origin and projected utilization.

- The applicant begins with the historical March 31, 2022 patient census.
- The applicant applies the Average Annual Change Rate (AACR) published in the 2022 SMFP, 0.4%, for predicting growth of the Granville County patients.

- The applicant assumes the 17 in-center patients residing in Durham, Franklin, Vance, Wake, and Warren Counties will continue to dialyze at FMC Neuse River and does not project any growth.
- The proposed new stations are projected to be certified as of December 31, 2023.
- Operating Year (OY) 1, the first full FY is CY2024. OY2 is CY2025.

The applicant's assumptions are reasonable and adequately supported.

### **Analysis of Need**

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

*“The need that this population has for the proposed services is a function of the individual patient need for dialysis care and treatment. This question specifically addresses the need that the population to be served has for the proposed project. The applicant has identified the population to be served as 75.6 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 70.0%, or 2.8 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 applies the County AACR as provided in the 2022 SMFP to project growth in Granville County patient utilization and projects no growth for the patients from other counties being served at FMC Neuse River.
- The applicant assumes the out-of-state patient will continue to dialyze at the facility.
- The applicant's need analysis results in utilization which exceeds the minimum required by the performance standard.

### **Projected In-Center Utilization**

In Section Q Form C, page 83, the applicant provides the projected utilization, as summarized in the following table.

**Form C Utilization as Provided by Applicant in Section Q**

<b>Form C Utilization</b>	<b>Last Full FY CY2021</b>	<b>1st Full FY CY2024</b>	<b>2nd Full FY CY2025</b>
<b><i>In-Center Patients</i></b>	77	75	76
# of Patients at the Beginning of the Year	74	76	76
# of Patients at the End of the Year	76	76	76
Average # of IC Patients during the Year	148	148	148
# of Treatments / Patient / Year	10,952	11,177	11,212
<b><i>Peritoneal Dialysis Patients</i></b>			
# of Patients at the Beginning of the Year	8	6	6
# of Patients at the End of the Year	3	6	6
Average # of IC Patients during the Year	6	6	6
# of Treatments / Patient / Year	848	896	900
<b><i>Total Patients</i></b>	148	148	148
<b><i>Total # of Treatments</i></b>	<b>11,800</b>	<b>12,073</b>	<b>12,112</b>

In Section C, pages 26-27 and Section Q, pages 84-85, the applicant provides the assumptions and methodology used to project in-center utilization, which are summarized below.

- The first full FY is CY2024, the period from January 1, thru December 31, 2024
- The second full FY is CY2025.
- Projections begin with the facility census as of March 31, 2022.
- The applicant grows the Granville County patient census by 0.4%, the 5-year AACR, as found in the 2022 SMFP page 136.
- The out-of-state patients are assumed to continue to dialyze at the facility.
- The proposed new stations will be installed and certified as of December 31, 2023.

The applicant provides a table in Section C, page 27, and in Section Q, page 85, illustrating the application of its assumptions and methodology, as summarized below.

<b>FMC Neuse River In-Center Patients</b>	
Begin with the Granville County patient population as of March 31, 2022.	58
Project the Granville County patient population forward nine months to December 31, 2022, using the Five-Year AACR (.004%).	$58 \times 1.003 = 58.2$
Add the 17 patients from other counties. This is the ending census for Interim Year 1.	$58.2 + 17 = 75.2$
Project the Granville County patient population forward one year to December 31, 2023, using the Five-Year AACR.	$58.2 \times 1.004 = 58.4$
Add the 17 patients from other counties. This is the ending census for Interim Year 2.	$58.4 + 17 = 75.4$
Project the Granville County patient population forward one year to December 31, 2024, using the Five-Year AACR.	$58.4 \times 1.004 = 58.6$
Add the 17 patients from other counties. This is the projected ending census for Operating Year 1.	$58.6 + 17 = 75.6$
Project the Granville County patient population forward one year to December 31, 2025, using the Five-Year AACR.	$58.6 \times 1.004 = 58.9$
Add the 17 patients from other counties. This is the projected ending census for Operating Year 2.	$58.9 + 17 = 75.9$

Totals may not sum due to rounding

As shown in the table above, the applicant projects FMC Neuse River will serve 76 in-center patients by the end of the first full fiscal year of operation, (ending December 31, 2024), for a utilization rate of 2.81 patients per station per week or 70% ( $76 \text{ patients} / 27 \text{ stations} = 2.81$  patients per station per week,. The projected utilization of 2.81 patients per station per week for OY1 satisfies the 2.8 in-center patients per station threshold for the first year following completion of the project, as required by 10A NCAC 14C .2203(b).

*Projected Peritoneal Dialysis (PD) Utilization*

<b>FMC Neuse River Home Peritoneal Methodology</b>	
Begin with the Granville County patient population as of March 31, 2022.	6
Project the Granville County patient population forward nine months to December 31, 2022, using the Five-Year AACR (.004%).	$6 \times 1.003 = 6.024$
Project the Granville County patient population forward one year to December 31, 2023, using the Five-Year AACR.	$6.0 \times 1.004 = 6.0$
Project the Granville County patient population forward one year to December 31, 2024, using the Five-Year AACR.	$6.0 \times 1.004 = 6.1$
Project the Granville County patient population forward one year to December 31, 2025, using the Five-Year AACR.	$6.0 \times 1.004 = 6.1$

As shown in the table above, the applicant projects FMC Neuse River will serve 6 peritoneal patients by the end of the first full fiscal year of operation per week for OY1 peritoneal for the first year following completion of the project.

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

- The applicant bases the beginning in-center patient census on the ending census as of March 31, 2022, the most recent historical patient census, as submitted to the DHSR HealthCare Planning Section.
- The applicant projects the growth of the Granville County patient census using the Five-Year AACR of 0.04% as reported in the 2022 SMFP.
- The projected utilization rate by the end of OY1 exceeds the minimum standard of 2.8 patients per station per week.

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

In Section C.6, page 33, the applicant discusses access to the facility’s services, stating:

*“Fresenius Medical Care operates more than 100 dialysis facilities across North Carolina. Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.*

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

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

The applicant provides the estimated percentage for each medically underserved group to be served in the second year of operation on page 33, as summarized in the following table.

<b>Medically Underserved Groups</b>	<b>Percentage of Total Patients</b>
Low income persons	34.94%
Racial and ethnic minorities	16.87%
Women	33.73%
Persons with Disabilities	22.89%
Persons 65 and older	45.78%
Medicare beneficiaries	44.58%
Medicaid recipients	34.94%

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

- The Fresenius corporate policy commits to provide services to all patients referred for ESRD services.
- Fresenius' facilities have historically provided care to all in need of ESRD services, including underserved persons.

### **Conclusion**

The Agency reviewed the:

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

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

- The applicant adequately identifies the population to be served
- The applicant adequately explains why the population to be served needs the services proposed in this application
- Projected utilization is reasonable and adequately supported
- The applicant describes the extent to which all residents, including underserved groups, are likely to have access to the proposed services and adequately supports its assumptions

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

NA

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

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

C

The applicant proposes to add no more than two dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 27 stations upon project completion.

In Section E, page 42, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the status quo – The applicant states that failure to apply for additional stations leads to higher utilization rates and can lead to interruption of patient admission; thus, this alternative is not the most effective.
- Add more than two stations - The applicant states that the facility cannot accommodate more stations there is no room; thus, this is not the most effective alternative.

Based on the explanations above, the applicant determined that its project as proposed is the most effective alternative.

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

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

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information 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 the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Bio-Medical Applications of North Carolina, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. Pursuant to Condition 2 of the facility need determination in the 2022 SMFP, the certificate holder shall develop no more than two additional in-center dialysis stations for a total of no more 27 stations upon completion of the 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 on March 1, 2023.**
- 4. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to add no more than two dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 27 stations upon completion of the project.

**Capital and Working Capital Costs**

In Section Q, Form F.1a Capital Cost, the applicant projects the total capital cost for the project as shown in the table below.

Non-Medical Equipment	\$1,500
Furniture	\$6,000
<b>Total</b>	<b>\$7,500</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 accounts for specific costs related to each station.
- The applicant has knowledge and experience in calculating costs related to ESRD stations.

In Section F, page 46, the applicant states there will be no start-up or initial operating expenses associated with the proposed project since this is an existing facility that is already operational.

**Availability of Funds**

In Section F, page 44 the applicant states that the capital cost will be funded as shown in the table below.

**Sources of Capital Cost Financing**

Type	Biomedical Applications of North Carolina, Inc.
Accumulated reserves or OE *	\$7,500
<b>Total Financing</b>	<b>\$7,500</b>

\* OE = Owner’s Equity

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

- Exhibit F-2 contains a letter dated July 15, 2022, from Senior Vice President and Treasurer for Fresenius Medical Care Holdings, Inc., parent company to Bio-Medical Applications of North Carolina, Inc., authorizing the use of accumulated reserves for the capital needs of the project.
- The applicant documents that it has adequate cash and assets to fund the capital cost of the proposed project.

**Financial Feasibility**

The applicant provides pro forma financial statements for the first two full operating years following completion of the project. In Form F.2, page 94, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as summarized in the table below.

**FMC Neuse River Projected Revenue and Operating Expenses**

	Interim Full FY	Interim Full FY	1 <sup>st</sup> Full FY	2 <sup>nd</sup> Full FY
	CY2022	CY2023	CY2024	CY2025
Total In-Center Treatments	11,780	12,183	12,221	12,260
Total Gross Revenues (Charges)	\$74,109,289	\$76,645,875	\$76,885,422	\$77,125,927
Total Net Revenue	\$3,370,231	\$3,460,560	\$3,471,493	\$3,482,469
Avg Net Revenue per Treatment	\$286	\$284	\$284.	284
Total Operating Expenses (Costs)	\$2,913,694	\$3,163,046	\$3,290,930	\$3,324,164
Avg Op. Expense per Treatment	\$247	\$259	\$269	\$271
Net Income	\$456,880	\$297,515	\$180,563	\$158,305

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

- Contractual adjustments are calculated by payor class for each year.
- Salaries are projected to increase at 2% annually.
- 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 because the applicant adequately demonstrates the financial feasibility of the proposal is based upon reasonable projections of costs and charges for all the reasons described above.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

### C

The applicant proposes to add no more than two dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 27 stations upon project completion.

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

According to Table 9A on page 125 of the 2022 SMFP and the information provided by the applicant in Section G, page, 51, there are 2 existing dialysis facilities in Granville County, both of which are owned and operated by BMA. Information on these dialysis facilities, from Table 9A of the 2022 SMFP is summarized below.

<b>Granville County Dialysis Facilities Certified Stations and Utilization as of December 31, 2020</b>				
<b>Dialysis Facility</b>	<b># Certified Stations*</b>	<b>#IC Patients**</b>	<b>Utilization***</b>	<b>Patients /Station</b>
FMC Dialysis Services Neuse River	25	77	77%	3.08
FMC Dialysis Services of Oxford	25	85	85%	3.40

Source Table 9A, 2022 SMFP.

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 Granville County. The applicant states that this application is based upon facility performance and demonstrated need at FMC Neuse River and is not specific to Granville County as a whole. The overall utilization for facilities in Granville County was approximately 74%.

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 applicant adequately demonstrates that FMC Neuse River needs additional stations to serve its existing and projected patient population.
- The applicant adequately demonstrates that the proposed additional stations are needed in addition to the existing and approved stations in the 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 based on the reasons stated above.

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

C

The applicant proposes to add no more than two dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 27 stations upon project completion.

In Section Q Form H, page 53-54, the applicant provides current and projected full-time equivalent (FTE) positions for the FMC Neuse River facility, as summarized in the following table:

POSITION	FTE POSITIONS CY2022	FTE POSITIONS CY2023	FTE POSITIONS 1 <sup>ST</sup> FY 2024	FTE Positions 2nd FY 2025
Administrator	1.00	1.00	1.00	1.00
RN	2.00	2.00	2.00	2.00
Patient Care Technician (PCT)	8.00	8.00	8.00	8.00
Dietician	0.00	1.00	2.00	2.00
Social Worker	1.00	2.00	2.00	2.00
Maintenance	1.00	1.00	1.00	1.00
Administration/Business Office	1.00	1.00	1.00	1.00
FMC Director Operations	0.14	0.14	0.14	0.14
FMC Chief Technician	0.15	0.15	0.15	0.15
FMC In-Service	0.20	0.20	0.20	0.20
<b>Total</b>	<b>14.49</b>	<b>16.49</b>	<b>17.49</b>	<b>17.49</b>

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 in regard to recruitment, 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 the reasons stated above.

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

The applicant proposes to add no more than two dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 27 stations upon project completion.

### **Ancillary and Support Services**

In the table in Section I, page 55, the applicant identifies each ancillary and support service listed in the application as necessary for the proposed services. On pages 55-60, the applicant explains how each ancillary and support service is made available.

The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the services the applicant currently provides at FMC Neuse River.

### **Coordination**

In Section I, page 60, the applicant describes its existing relationships with other local health care and social service providers.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant discusses its existing relationships with local health care and social service providers
- The applicant has agreements in place coordinating lab services, hospital services, and transplant 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.

- (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 any construction or renovation. Therefore, Criterion (12) is not applicable.

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

C

In Section L, page 68, the applicant provides the historical payor mix for in-center dialysis during CY2021 for FMC Neuse River, as summarized in the table below.

Primary Payor Source at Admission	In-center Dialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total
Self-Pay	0.3	0.42%	0.0	0.00%
Insurance *	4.3	5.80%	0.1	2.36%
Medicare *	61.4	83.01%	2.9	97.64%
Medicaid *	3.8	5.17%	0.	0.00%
Other (Misc. including VA)	4.1	5.59%	0.	0.00%
<b>Total</b>	<b>74.0</b>	<b>100.0%</b>	<b>3.0</b>	<b>100.00</b>

\*Including any managed care plans

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

FMC Dialysis Services Neuse River LFOY	Percentage of Total Patients Served by the Facility	Percentage of the Population of the Service Area
Female	44.7%	49.5%
Male	55.3%	50.5%
64 and Younger	44.7%	80.3%
65 and Older	53.3%	19.7%
American Indian	0.0%	0.7%
Asian	0.0%	2.9%
Black or African American	47.0%	21.4%
Native Hawaiian/Pacific Islander	0.0%	0.2%
White or Caucasian	51.5%	71.8%
Other Race	0.0%	10.6%

The Agency reviewed the:

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

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

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and persons with disabilities to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 70, the applicant states that FMC is not obligated under any applicable federal regulations to provide uncompensated care, community service, or access by minorities and persons with disabilities.

In Section L, page 70, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against the facility identified in Section A, Question 4.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L.3, page 71, the applicant projects the payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as summarized in the table below.

**FMC Dialysis Services Neuse River Projected Payor Mix  
 Second Full FY of Operation following Project Completion  
 CY2025**

County	IC Patients		Peritoneal Dialysis	
	Patients	% of Total	% Patients	% of Total
Self-Pay	0.3	0.42%	0.0	0.00%
Insurance *	4.4	5.80%	0.1	2.36%
Medicare *	63.0	83.01%	5.9	97.64%
Medicaid *	3.9	5.17%	0.0	0.00%
Other (Misc., including VA)	4.2	5.59%	0.0	0.00%
<b>Total</b>	<b>75.9</b>	<b>100.0%</b>	<b>6.1</b>	<b>100.00%</b>

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

As shown in the table above, during the second full fiscal year of operation, the applicant projects in-center services as follows: 0.42% will be provided to self-pay patients, 83.01% to Medicare recipients and 5.17% to Medicaid recipients. The applicant projects peritoneal dialysis services as follows: 97.64% to Medicare recipients.

On page 71, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- The applicant bases payor mix upon treatment volumes rather than patients.
- The applicant bases future payor mix percentages on recent facility performance.

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section L, page 72, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to add no more than two dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 27 stations upon project completion.

In Section M, page 74, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-1. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- The applicant currently provides applicable health professional training programs in the area with access to the facility.
- The applicant provides a copy of the letter sent to Granville Community College offering training opportunities in Exhibit M-1.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.  
(16) Repealed effective July 1, 1987.  
(17) Repealed effective July 1, 1987.  
(18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case

of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to add no more than two dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 27 stations upon project completion.

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

Information on the Granville County dialysis facilities, from Table 9A of the 2022 SMFP, is summarized below:

<b>Granville County Dialysis Facilities Certified Stations and Utilization as of December 31, 2020</b>				
<b>Dialysis Facility</b>	<b># Certified Stations*</b>	<b>#IC Patients</b>	<b>Utilization</b>	<b>Patients /Station</b>
FMC Neuse River	25	77	77%	3.08
FMC Dialysis Services Oxford	25	85	85%	3.40

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 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 2022 SMFP.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, pages 75-76, the applicant states:

*“Fresenius Medical Care related facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid.*

...

*Fresenius Medical Care related facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients.*

...

*Approval of this application will allow the facility to continue serving patients residing in the area of the facility. 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 B, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 75, 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. Our organizational mission statement captures this sentiment very well:*

*‘We deliver superior care that improves the that quality of life of every patient, every day, setting the standard by which others in the healthcare industry are judged.’”*

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 75, the applicant states:

*“It is corporate policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, or any other factor that would classify a patient as underserved.*

*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 Sections B, 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 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 the reasons stated above.

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

### C

In Section Q Form O, 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 over 120 dialysis facilities owned, operated, or managed by a Fresenius Medical Care related entity and located in North Carolina.

In Section O, page 81, the applicant states that, during the 18 months immediately preceding the submittal of the application, no Fresenius related facility has been found to have had an incident related to quality of care that resulted in a finding of "*Immediate Jeopardy*". After reviewing and considering information provided by the applicant and considering the quality of care provided at all Fresenius facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

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 application is conforming with all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. The specific criteria are discussed below.

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

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

-NA- FMC Neuse River 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, pages 25-26, and on Section Q Form C Utilization, the applicant projects that FMC Neuse River will serve 77 in-center patients on 25 stations, a utilization rate of 3.08 ( $77 / 25 = 3.08$ ) patients per station per week, as of the end of the first operating year following project completion, exceeding the 2.8 patients per station per week requirement. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

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