

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: December 17, 2021

Findings Date: December 17, 2021

Project Analyst: Gregory F. Yakaboski

Co-Signer: Lisa Pittman

Project ID #: P-12104-21

Facility: FMC of Kinston Dialysis Unit

FID #: 955898

County: Lenoir

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

Project: Add no more than three dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 42 stations upon project completion

REVIEW CRITERIA

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

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

C

Bio-Medical Applications of North Carolina, Inc. (hereinafter "BMA" or "the applicant") proposes to add no more than three dialysis stations to FMC of Kinston Dialysis Unit (FMC Kinston) pursuant to Condition 2 of the facility need methodology for a total of no more than 42 stations upon project completion. Fresenius Medical Care Holdings, Inc. (Fresenius) is the ultimate parent company of BMA.

FMC provides in-center (IC) dialysis, a peritoneal dialysis (PD) program, and a home hemodialysis (HH) program. The number of dialysis stations at an ESRD facility include both IC dialysis and HH dialysis, if the facility offers HH dialysis.

Need Determination

Chapter 9 of the 2021 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table 9C, page 137, the county need methodology shows there is not a county need determination for additional dialysis stations in Lenoir 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 2021 SMFP, if the utilization rate for the dialysis center as reported in the 2021 SMFP is at least 75 percent or 3.0 patients per station per week, as stated in Condition 2.a. Table 9A on page 125 of the 2021 SMFP shows the utilization rate reported for FMC Kinston is 75.0 percent or 3.0 patients per station per week based on 117 in-center dialysis patients and 39 certified dialysis stations (117 patients / 39 stations = 3.0; $3.0 / 4 = 0.75$ or 75%).

As shown in Table 9D on page 139 of the 2021 SMFP, based on the facility need methodology for dialysis stations, the potential number of stations needed at FMC Kinston is up to three additional stations; thus, the applicant is eligible to apply to add up to three stations during the 2021 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant has not previously applied to add dialysis stations to FMC Kinston during the 2021 SMFP review cycle.

The applicant proposes to add no more than three new stations to FMC Kinston, which is consistent with the 2021 SMFP calculated facility need determination for up to three dialysis stations; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

Policies

There is one policy in the 2021 SMFP which is applicable to this review. *Policy GEN-3: Basic Principles*, on page 29 of the 2021 SMFP, states:

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

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

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

Conclusion

The Agency reviewed the:

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

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

- The applicant adequately demonstrates that the application is consistent with Condition 2 of the facility need methodology as applied from the 2021 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 expended.

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

C

The applicant proposes to add no more than three dialysis stations at FMC Kinston pursuant to Condition 2 of the facility need methodology for a total of no more than 42 stations upon completion of this project.

Patient Origin

On page 113, the 2021 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 area: Cherokee, Clay, and Graham counties and Avery, Mitchell, and Yancey counties.” FMC Kinston is Lenoir County. Thus, the service area for this application is Lenoir County. Facilities may serve residents of counties not included in their service area.

The following table illustrates historical and projected patient origin at FMC Kinston.

FMC Kinston: Current & Projected Patient Origin												
County	Current – CY 2020						Projected – CY 2024					
	IC Patients		HH Patients		PD Patients		IC* Patients		HH Patients		PD Patients	
	#	%	#	%	#	%	#	%	#	%	#	%
Lenoir	102.0	95.3%	10.0	100.0%	13.0	92.9%	130.7	96.3%	12.8	100.0%	16.7	94.3%
Craven	2.0	1.9%					2.0	1.5%				
Duplin	1.0	0.9%					1.0	0.7%				
Greene	2.0	1.9%			1.0	7.1%	2.0	1.5%			1.0	5.7%
Total	107.0	100.0%	10.0	100.0%	13.0	100.0%	135.7	100.0%	12.8	100.0%	17.7	100.0%

Note: Table may not foot due to rounding.

Source: Section C, pages 25-26

In Section C.3, pages 26-27, and the Form C Utilization subsection of Section Q, the applicant provides the assumptions and methodology used to project patient origin. The applicant’s assumptions are reasonable and adequately supported based on the following:

- The applicant clearly explains how it projected growth in the Lenoir’s County patient population.
- The applicant did not project growth in the number of patients at FMC Kinston who do not live in Lenoir County.

Analysis of Need

In Section C, page 17 and pages 26-27, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services.

- On page 17, the applicant states that the proposed addition of three dialysis stations at FMC Kinston are needed based on Condition 2 of the Facility Need Methodology, 2021 SMFP.

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

- According to the 2021 SMFP, Table 9A, as of December 31, 2019, FMC Kinston was operating at a rate of 3.0 in-center patients per station per week, or at a utilization rate of 75.0 percent [117 patients / 39 stations = 3.0; 3.0/ 4 = 0.75 or 75.0%].
- The applicant demonstrates eligibility to add dialysis stations to its facility under

Condition 2 of the facility need methodology. The discussion regarding need methodology found in Criterion (1) is incorporated herein by reference.

- The applicant projects 127 IC patients dialyzing at FMC Kinston as of December 31, 2023, the end of the first Operating Year (OY). This equates to a utilization rate of 72.35% or 2.89 patients per station per week [$127.9 / 42 \text{ stations} = 3.05$; $3.06 / 4 = 0.7625$ or 76.25%].

Projected Utilization

In-Center Utilization

In Section C, page 27, and Section Q, Form C, the applicant provides projected utilization, as illustrated in the following table.

The applicant begins with the Lenoir County IC patients as of January 1, 2021.	102
The applicant projects Lenoir County IC patients forward one year to December 31, 2021 using the Lenoir County Five Year Average Annual Change Rate (AACR) of 6.4%.	$102 \times 1.064 = 108.5$
The applicant projects Lenoir County IC patients forward one year to December 31, 2022 using the Lenoir County Five Year AACR.	$108.5 \times 1.064 = 115.5$
The applicant projects Lenoir County IC patients forward one year to December 31, 2023 using the Lenoir County Five Year AACR.	$115.5 \times 1.064 = 122.9$
The applicant adds the 5 non-Lenoir County IC patients. This is the projected ending census for Operating Year 1 (CY2023) .	$122.9 + 5 = \mathbf{127.9}$
The applicant projects Lenoir County IC patients forward one year to December 31, 2023 using the Lenoir County Five Year AACR.	$122.9 \times 1.064 = 130.7$
The applicant adds the 4 non-Lenoir County IC patients. This is the projected ending census for Operating Year 2 (CY2024) .	$130.7 + 5 = \mathbf{135.7}$

Therefore, at the end of OY1 (CY2023) the facility is projected to serve 127.9 in-center patients and at the end of OY2 (CY2024) the facility is projected to serve 135.7 in-center patients.

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

- OY1: 3.05 patients per station per week or 76.25% utilization ($127.9 \text{ patients} / 42 \text{ stations} = 3.05 / 4 = 0.7625$ or 76.25%)
- OY2: 3.23 patients per station per week or 80.75% utilization ($135.7 \text{ patients} / 42 \text{ stations} = 3.23 / 4 = 0.8075$ or 80.75%)

The projected utilization of 3.05 patients per station per week at the end of OY1 exceeds the minimum standard of 2.8 in-center patients per station per week required by 10A NCAC 14C .2203(b).

In Section C, pages 26-27 and Section Q, Form C, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The applicant projects the first two full operating years of the project will be January 1, 2023–December 31, 2023 (CY2023) and January 1, 2024–December 31, 2024 (CY2024).
- The applicant begins its projections with the facility census as of December 31, 2020. This information is reported in the ESRD Data Collection forms submitted to the Agency. The facility reported 107 in-center patients receiving dialysis services at FMC Kinston. Of the 107 patients, 102 reside in Lenoir County and 5 are non-Lenoir County residents.
- The applicant applied a projected annual growth rate of 6.4% for the Lenoir County patients based on the Lenoir County Five-Year AACR of 6.4%, as published in the 2021 SMFP.
- The applicant does not project growth for the 5 patients residing outside of the Lenoir County service area.

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

- The applicant projects future utilization based on the most recent historical patient census.
- The applicant applied a projected annual growth rate of 6.4% for the patients from Lenoir County based on the Lenoir County Five-Year AACR of 6.4%, as published in the 2021 SMFP.
- The applicant does not project growth for its IC patients who do not reside in Lenoir County.
- Projected utilization for the in-center patients at the end of OY1 exceeds the minimum of 2.8 patients per station per week required by 10A NCAC 14C .2203(b).

PD Utilization

FMC Kinston: HH Projected Utilization	
Starting point of calculations is Lenoir County HH patients dialyzing at FMC Kinston as of January 1, 2021.	13
Lenoir County patient population is projected forward by one year to December 31, 2021 using the Lenoir County Five Year Average Annual Change Rate (AACR) of 6.4%.	$13 \times 1.064 = 13.8$
Lenoir County patient population is projected forward by one year to December 31, 2022 using the Lenoir County Five Year AACR of 6.4%.	$13.8 \times 1.064 = 14.7$
Lenoir County patient population is projected forward by one year to December 31, 2023 using the Lenoir County Five Year AACR of 6.4%.	$14.7 \times 1.064 = 15.7$
The applicant adds the one patient from Greene County. This is the projected ending census for Operating Year 1 (CY2023) .	$15.7 + 1 = 16.7$
Lenoir County patient population is projected forward by one year to December 31, 2024 using the Lenoir County Five Year AACR of 6.4%.	$15.7 \times 1.064 = 16.7$
The applicant adds the one patient from Greene County. This is the projected ending census for Operating Year 2 (CY2024) .	$16.7 + 1 = 17.7$

HH Utilization

FMC Kinston: HH Projected Utilization	
Starting point of calculations is Lenoir County HH patients dialyzing at FMC Kinston as of January 1, 2021.	10
Lenoir County patient population is projected forward by one year to December 31, 2021 using the Lenoir County Five Year Average Annual Change Rate (AACR) of 6.4%.	$10 \times 1.064 = 10.6$
Lenoir County patient population is projected forward by one year to December 31, 2022 using the Lenoir County Five Year AACR of 6.4%.	$10.6 \times 1.064 = 11.3$
Lenoir County patient population is projected forward by one year to December 31, 2023 using the Lenoir County Five Year AACR of 6.4%. This is the projected ending census for Operating Year 1 (CY2023) .	$11.3 \times 1.064 = 12.0$
Lenoir County patient population is projected forward by one year to December 31, 2024 using the Lenoir County Five Year AACR of 6.4%. This is the projected ending census for Operating Year 2 (CY2024) .	$12.0 \times 1.064 = 12.8$

Projected utilization for PD and HH patient utilization is reasonable and adequately supported based on the following:

- The applicant projects future utilization based on the most recent historical patient census.
- The applicant applied a projected annual growth rate of 6.4% for the patients from Lenoir County based on the Lenoir County Five-Year AACR of 6.4%, as published in the 2021 SMFP.
- The applicant does not project growth for its PD patient who does not reside in Lenoir County.

Access to Medically Underserved Groups

In Section C.6, page 32, the applicant states:

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

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, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low income persons	45.2%
Racial and ethnic minorities	81.5%
Women	51.9%
Persons with Disabilities	22.2%
Persons 65 and older	43.0%
Medicare beneficiaries	74.8%
Medicaid recipients	45.2%

Source: Section C, page 32.

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 all the reasons described above.

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

NA

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

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

CA

The applicant proposes to add no more than three dialysis stations at FMC Kinston pursuant to Condition 2 of the facility need methodology for a total of no more than 42 stations upon completion of this 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 considered were:

- *Maintain the status quo* – the applicant states that maintaining the status quo, or not applying for additional stations, would result in utilization rates of 3.28 patients per station (82.0% utilization) by the end of operating year one and 3.48 patients per station (87.0% utilization) by the end of operating year two. Therefore, the applicant states this alternative is less effective.
- *Add fewer stations* – the applicant states that this alternative would also result in higher utilization rates and potentially interrupt patient admissions.; therefore, the applicant determined that this was not the most effective alternative.

Based on the explanations above, the applicant states that its proposal is the most effective alternative because it will enable FMC Kinston to accommodate the existing patients and projected patients without the potential of interrupting patient admissions.

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

- The 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 2021 SMFP, the certificate holder shall develop no more than three additional in-center (and home hemodialysis) dialysis stations for a total of no more 42 in-center (and home hemodialysis) stations at FMC Kinston 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. Progress reports shall be due on the first day of every third month. The first progress report shall be due on January 1, 2022. The second progress report shall be due on April 1, 2022 and so forth.**
- 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 three dialysis stations at FMC Kinston pursuant to Condition 2 of the facility need methodology for a total of no more than 42 stations upon completion of this project.

Capital and Working Capital Costs

In Section Q Form F.1a Capital Cost, page 87, the applicant projects the total capital cost of the project, as summarized below.

Site Costs	\$0
Construction Costs	\$0
Furniture /Fixtures Costs	\$11,250
Total	\$11,250

In Section Q, page 87, 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:

- Cost of furniture and fixtures estimated based on experience purchasing furniture and fixtures at existing facilities.

In Section F.3, page 44, 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.2, page 42, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	Bio-Medical Applications of North Carolina, Inc.
Loans	\$0
Accumulated reserves or OE *	\$11,250
Bonds	\$0
Other (Specify)	\$0
Total Financing	\$11,250

* OE = Owner's Equity

Exhibit F-2 contains a letter dated July 15, 2021 from the Senior Vice President and Treasurer, authorizing and committing accumulated reserves of Fresenius Medical Care Holdings Inc., the parent company for BMA, for the capital costs of the project. The letter also documents that the 2020 Consolidated Balance Sheet for FMCH reflects more than \$446 million in cash, and total assets exceeding \$25 billion.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the 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, the applicant projects that revenues will exceed operating expenses in the first two operating years following completion of the project, as shown in the table below.

	1st Full Fiscal Year (CY2023)	2nd Full Fiscal Year (CY2024)
Total Treatments	22,502	23,885
Total Gross Revenues (Charges)	\$141,559,936	\$150,262,242
Total Net Revenue	\$6,266,614	\$6,651,995
Average Net Revenue per Treatment	\$278	\$279
Total Operating Expenses (Costs)	\$5,436,680	\$5,637,426
Average Operating Expense per Treatment	\$242	\$236
Net Income	\$829,934	\$1,014,569

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

- The applicant adequately explains the assumptions used to project revenue, such as projected reimbursement rates, and operating costs, such as salaries.
- Charges and expenses are based on historical facility operations projected forward.
- Payor percentages are based on historical facility operations.
- FTEs and salaries are based on current staffing and projected to average annual salary increases of 2.0%
- 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
 - The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the proposal
 - The applicant adequately demonstrates the availability of sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges
- (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 three dialysis stations at FMC Kinston pursuant to Condition 2 of the facility need methodology for a total of no more than 42 stations upon completion of this project.

On page 113, the 2021 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 area: Cherokee, Clay, and Graham counties and Avery, Mitchell, and Yancey counties.*” FMC Kinston is Lenoir County. Thus, the service area for this application is Lenoir County. Facilities may serve residents of counties not included in their service area.

According to Table 9A of the 2021 SMFP, there are two existing or approved dialysis facilities in Lenoir County, both of which are owned and operated by Fresenius. Information on these dialysis facilities, from Table 9A of the 2021 SMFP, is provided below:

Lenoir County Dialysis Facilities				
Certified Stations and Utilization as of December 31, 2019				
Dialysis Facility	Owner	Location	# of Certified Stations	Utilization
FMC of Kinston Dialysis Unit	Fresenius	Kinston	39	75.00%
FMC Vernon Dialysis	Fresenius	Kinston	24	84.38%

Source: 2021 SMFP, Chapter 9, Table 9A, pages 125.

In Section G, page 49, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Lenoir County. The applicant states:

“This is an application based upon the facility performance and demonstrated need at the FMC Kinston. The need addressed by this application is not specific to Lenoir County as a whole.”

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 reasons:

- The applicant adequately demonstrates that the proposed three new in-center dialysis stations at FMC Kinston in Lenoir County is based on, and in compliance with, Condition 2 of the facility need methodology in the 2021 SMFP.
- The applicant adequately demonstrates that the proposed dialysis stations are needed in addition to the existing or approved dialysis stations in Lenoir County.

Conclusion

The Agency reviewed the:

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

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

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

C

The applicant proposes to add no more than three dialysis stations at FMC Kinston pursuant to Condition 2 of the facility need methodology for a total of no more than 42 stations upon completion of this project.

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

POSITION	Current FTE Positions	FTE POSITIONS OY1	FTE POSITIONS OY2
Administrator	1.00	1.00	1.00
RN	5.10	6.10	6.10
Home Training Nurse	3.00	3.00	3.00
Patient Care Technician (PCT)	10.50	11.50	11.50
Dietician	1.10	1.10	1.10
Social Worker	1.00	1.00	1.00
Maintenance	1.00	1.00	1.00
Administration/Business Office	1.80	1.80	1.80
Director Operations	0.15	0.15	0.15
Chief Technician	0.15	0.15	0.15
FMC In-Service	0.15	0.15	0.15
Total	24.95	26.95	26.95

Source: Section Q Form H, page 97 .

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.2 and H.3, pages 51-52, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

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

- The 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, 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 three dialysis stations at FMC Kinston pursuant to Condition 2 of the facility need methodology for a total of no more than 42 stations upon completion of this project.

Ancillary and Support Services

In Section I, page 53, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 53-58, the applicant explains how each ancillary and support service is or will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant currently provides dialysis services at FMC Kinston with the necessary ancillary and support services
- The applicant states that it has agreements in place for lab services, hospital affiliation, and transplant services

Coordination

In Section I, page 58, the applicant describes its existing and proposed relationships with other local health care and social service providers.

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

- The applicant discusses its 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 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.

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

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

NA

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

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

NA

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

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

- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L, page 66, the applicant provides the historical payor mix during CY 2020 for the proposed services, as shown in the table below.

FMC Kinston: Historical Payor Mix CY 2020						
Payment Source	In-Center		HH		PD	
	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients
Self-Pay	1.1	1.0%	0.0	0.0%	0.2	1.6%
Insurance*	2.8	2.6%	1.5	14.8%	1.8	12.7%
Medicare*	88.3	82.6%	8.1	80.8%	9.8	70.3%
Medicaid*	8.5	8.0%	0.4	4.4%	1.1	8.0%
Misc. (including VA, Med. Adv.)	6.3	5.9%	0.0	0.0%	1.0	7.4%
Total	107	100.0%	10	100.0%	14	100.0%

*Including any managed care plans

In Section L, page 67, the applicant provides the following comparison.

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY2020	Percentage of the Population of the Service Area
Female	51.9%	52.2%
Male	48.1%	47.8%
Unknown	na	na
64 and Younger	57.0%	79.8%
65 and Older	43.0%	20.2%
American Indian	0.0%	0.6%
Asian	0.0%	0.7%
Black or African American	78.5%	41.4%
Native Hawaiian or Pacific Islander	0.0%	0.2%
White or Caucasian	21.5%	48.9%
Other Race	0.0%	8.2%
Declined / Unavailable	0.0%	0.0%

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 68, the applicant states it has no such obligation.

In Section L.2, page 68, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against FMC Kinston.

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 69, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation (CY2024) following completion of the project, as shown in the table below.

FMC Kinston: Projected Payor Mix 2nd FFY (CY 2024)						
	In-Center		HH		PD	
Payment Source	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients
Self-Pay	1.4	1.0%	0.0	0.0%	0.3	1.6%
Insurance*	3.5	2.6%	1.9	14.8%	2.2	12.7%
Medicare*	112.0	82.6%	10.4	80.8%	12.4	70.3%
Medicaid*	10.8	8.0%	0.6	4.4%	1.4	8.0%
Misc. (including VA, Med. Adv.)	8.0	5.9%	0.0	0.0%	1.3	7.4%
Total	135.7	100.0%	12.8	100.0%	17.7	100.0%

*Including any managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 1.0% of in-center services will be provided to self-pay patients, 82.6% to Medicare patients and 8.0% to Medicaid patients.

On page 69, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following reasons:

- The projected payor mix is based on the historical treatment volumes at FMC Kinston.
- Projections assume that there will be no changes to the payor mix as a result of this project.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 71, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to add no more than three dialysis stations at FMC Kinston pursuant to Condition 2 of the facility need methodology for a total of no more than 42 stations upon completion of this project.

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

- The applicant provides a copy of a letter sent to Lenoir Community College offering the facility as a training site for nursing students.
- The applicant states it often receives requests for information from program directors and individual students and, in response, the Center Manager discusses dialysis and ESRD for students and offers access to the patients and facility.

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 three dialysis stations at FMC Kinston pursuant to Condition 2 of the facility need methodology for a total of no more than 42 stations upon completion of this project.

On page 113, the 2021 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 area: Cherokee, Clay, and Graham counties and Avery, Mitchell, and Yancey counties.” FMC Kinston is Lenoir County. Thus, the service area for this application is Lenoir County. Facilities may serve residents of counties not included in their service area.

According to Table 9A of the 2021 SMFP, there are two existing or approved dialysis facilities in Lenoir County, both of which are owned and operated by Fresenius. Information on these dialysis facilities, from Table 9A of the 2021 SMFP, is provided below:

Lenoir County Dialysis Facilities				
Certified Stations and Utilization as of December 31, 2019				
Dialysis Facility	Owner	Location	# of Certified Stations	Utilization
FMC of Kinston Dialysis Unit	Fresenius	Kinston	39	75.00%
FMC Vernon Dialysis	Fresenius	Kinston	24	84.38%

Source: 2021 SMFP, Chapter 9, Table 9A, pages 125.

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

“The applicant does not expect this proposal to have any effect on the competitive climate in Lenoir 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 74, the applicant states:

“Approval of this application will allow the facility to continue serving patients who reside in the area. Consequently, these patients will have a shorter commute to and from dialysis treatment. This is an immediate and significantly positive impact to the patients of the area.”

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

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

“Quality of care is 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 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 74, the applicant states:

“It is corporate policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay 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.”

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 located in North Carolina.

In Section O, page 79, 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 publicly available data 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- The applicant does not propose to establish a new kidney disease treatment center or dialysis facility. Therefore, this Rule is not applicable to this review.

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

(1) *an existing dialysis facility; or*

(2) *a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need;*

shall document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the additional stations.

-C- In Section C, page 27, and on Section Q Form C Utilization, the applicant projects that FMC Kinston will serve 127.9 in-center patients on 42 stations, a utilization rate of 3.05 ($127.9 / 42 = 3.05$) patients per station per week, as of the end of the first operating year following project completion, which exceeds the required performance standard of 2.8 patients per station. 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 the Form C Utilization subsection of Section Q, 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.