

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: November 30, 2021

Findings Date: November 30, 2021

Project Analyst: Ena Lightbourne

Co-Signer: Micheala L. Mitchell

Project ID #: M-12101-21

Facility: FMC Dialysis Services North Ramsey

FID #: 960411

County: Cumberland

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

Project: Add no more than four dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 54 stations upon completion of this project and Project ID# M-11776-19 (add 10 stations)

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. (BMA or “the applicant”), proposes to add no more than four dialysis stations to the Fresenius Medical Care Dialysis Services North Ramsey (FMC Dialysis Services North Ramsey) facility pursuant to Condition 2 of the facility need methodology for a total of no more than 54 in-center (IC) dialysis stations upon completion of this project and Project ID# M-11776-19 (add 10 stations).

Need Determination (Condition 2)

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 9B, page 133, the county need methodology shows there is not a county need determination for additional dialysis stations in Cumberland 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 facility 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. The utilization rate reported for the facility is 81.86 percent or 3.27 patients per station per week, based on 167 in-center dialysis patients and 51 certified dialysis stations (167 patients / 51 stations = 3.27; $3.27 / 4 = 81.86\%$).

As shown in Table 9D, based on the facility need methodology for dialysis stations, the potential number of stations needed is up to 4 additional stations; thus, the applicant is eligible to apply to add up to 4 stations during the 2021 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

Policies

There is one policy in the 2021 SMFP that is applicable to this review, Policy GEN-3: *Basic Principles*.

Policy GEN-3, 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.”

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 73; Section O, pages 75-78; 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, pages 30-31; Section L, pages 65-70; Section N, page 73; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project will maximize healthcare value in Section B, pages 22-23; Section F, page 41; Section N, page 73; Section Q, page 85; 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.

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 2021 SMFP.
- The applicant adequately demonstrates that the application is consistent with Policy GEN-3 based on the following:
 - BMA facilities encourage all staff to provide quality care to every patient at every treatment as part of their quality care program.
 - BMA facilities have a history of providing 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 takes on the burden of completing the project by seeking funds through the applicant's parent company, Fresenius Medical Care and not through federal and state monies or charitable contributions.

(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.

The applicant proposes to add no more than four dialysis stations to FMC Dialysis Services North Ramsey facility pursuant to Condition 2 of the facility need methodology for a total of no more than 54 in-center (IC) dialysis stations upon completion of this project and Project ID# M-11776-19 (add 10 stations).

Patient Origin

On page 113, the 2021 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located.*” Thus, the service area for this facility consists of Cumberland County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates historical and projected patient origin.

FMC Dialysis Services North Ramsey Patient Origin				
County	Historical 01/01/2020-12/31/2020 (CY 2020)		Second Full FY of Operation following Project Completion 01/01/2024-12/31/2024 (CY 2024)	
	IC Patients	% of Total	IC Patients	% of Total
Cumberland	143	94.1%	175.1	96.7%
Harnett	6	3.9%	6	3.3%
Georgia	1	0.7%	0	0.0%
Other States	2	1.3%	0	0.0%
Total	143 [152]	100.0%	181.1	100.0%

Source: Section C, pages 25-26
 Note: Project Analyst’s calculation in brackets.

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

- The applicant begins its projections with the facility patient census as of December 31, 2020, as reported in the 2020 ESRD Data Collection Forms submitted to the Agency.
- The applicant projects growth of the Cumberland County patient census using the Cumberland Count Five-Year Average Annual Change Rate (AACR) of 5.2%, as published in the 2021 SMFP.
- The applicant assumes that the six IC patients residing in Harnett County, will continue dialysis at FMC Dialysis Services North Ramsey by choice and does not project any growth for this segment of the patient population.
- The applicant assumes that the patients residing in Georgia and other states, dialyzing at the facility were transient patients and does not project any growth for this segment of the patient population.

- The project is scheduled for completion on December 31, 2022. 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).

Analysis of Need

In Section C, page 28, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 28, 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 addressed the need that the population to be served has for the proposed project. The applicant has identified the populations to be served as 172.5 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 79.86%, or 3.19 patients per station and exceeds the minimum required by the performance standard.”

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

- The applicant demonstrates eligibility to add dialysis stations to its facility under Condition 2 of the facility need methodology. See the discussion regarding need methodology found in Criterion (1) which is incorporated herein by reference.
- The applicant projects a utilization rate of 3.19 IC patients per station per week dialyzing at FMC Dialysis Services North Ramsey as of the end of the first 12 months of operation following certification of the additional stations which exceeds the performance standards of 2.8 IC patients per station per week as of the end of the first 12 months of operation following certification of the additional stations as set forth in the Performance Standards in Rule 10A NCAC 14C .2203.

Projected Utilization

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

FMC Dialysis Services North Ramsey	
Begin with the Cumberland County patient population as of December 31, 2020.	143
Project the Cumberland County patient population forward for one year to December 31, 2021, using the Cumberland County Five-Year AACR.	$143 \times 1.052 = 150.4$
Project the Cumberland County patient population forward one year to December 31, 2022.	$150.4 \times 1.052 = 158.3$
Add the six patients from Harnett County. This is the projected starting census for this project.	$158.3 + 6 = 164.3$
Project the Cumberland County patient population forward for one year to December 31, 2023.	$158.3 \times 1.052 = 166.5$
Add the six patients from Harnett County. This is the projected ending census for Operating Year 1.	$166.5 + 6 = 172.5$
Project the Cumberland County patient population forward for one year to December 31, 2024.	$166.5 \times 1.052 = 175.1$
Add the six patients from Harnett County. This is the projected ending census for Operating Year 2.	$175.1 + 6 = 181.1$

Projected patients for OY1 and OY2 are rounded to the nearest whole number. Therefore, at the end of OY1 (CY2023) the facility is projected to serve 173 IC patients and at the end of OY2 (CY2024) the facility is projected to serve 181 IC patients.

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

- OY1: 3.19 patients per station per week or 82.78% ($172.5 \text{ patients} / 54 \text{ stations} = 3.1944/4 = 0.7986$ or 79.86%)
- OY2: 3.35 patients per station per week or 88.89% ($181.1 \text{ patients} / 54 \text{ stations} = 3.3537/4 = 0.8384$ or 83.84%)

The projected utilization of 3.19 patients per station per week at the end of OY1 exceeds the minimum standard of 2.8 IC patients per station per week required by 10A NCAC 14C .2203(b).

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

- The applicant is proposing to add four stations to FMC Dialysis Services North Ramsey for a total of 54 stations upon completion of this project and Project ID# M-11776-19 (approved to add 10 stations).
- The applicant begins its projections with the facility patient census as of December 31, 2020, as reported in the 2020 ESRD Data Collection Forms submitted to the Agency.
- The applicant projects growth of the Cumberland County patient census using the Cumberland County Five-Year Average Annual Change Rate (AACR) of 5.2%, as published in the 2021 SMFP.

- The applicant assumes that the six IC patients residing in Harnett County, will continue dialysis at FMC Dialysis Services North Ramsey by choice and does not project any growth for this segment of the patient population.
- The applicant assumes that the patients residing in Georgia and other states, dialyzing at the facility were transient patients and does not project any growth for this segment of the patient population.
- The project is scheduled for completion on December 31, 2022. 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).

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

- The applicant projects future utilization based on the patient census as of December 31, 2020.
- The applicant utilized a projected annual growth rate of 5.2% for Cumberland County patients which reflects the Cumberland County Five-Year AACR, as published in the 2021 SMFP.
- The applicant does not project growth for three IC patients residing in Georgia and other states.
- Projected utilization at the end of OY1 exceeds the minimum of 2.8 IC patients per station per week required by 10A NCAC 14C .2203(b).

Access to Medically Underserved Groups

In Section C, page 30, the applicant states:

“The applicant, and its parent organization, Fresenius Medical Care, has a long history of providing dialysis services to the underserved populations of North Carolina.”

The applicant provides the estimated percentage for each medically underserved group during the second full fiscal year, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low income persons	66.1%
Racial and ethnic minorities	90.9%
Women	62.0%
Persons with Disabilities	51.2%
The elderly	60.3%
Medicare beneficiaries	90.9%
Medicaid recipients	47.9%

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 applicant's parent company operates more than 100 dialysis facilities in North Carolina that has a patient population that includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.
- The applicant's corporate policy is to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, or health insurer.

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 four dialysis stations to FMC Dialysis Services North Ramsey facility pursuant to Condition 2 of the facility need methodology for a total of no more than 54 in-center (IC) dialysis stations upon completion of this project and Project ID# M-11776-19 (add 10 stations).

In Section E, page 40, 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:

Not Applying for Additional Stations at FMC Dialysis Services North Ramsey-The applicant states that not applying for additional stations at the facility would result in higher utilization rates. The applicant projects that the facility's utilization rate at the end of Operating Year 1 will be 3.19 patients per stations, based upon 54 stations.

Apply for Fewer than Four Stations-The applicant states that applying for fewer stations will lead to higher utilization rates as the facility patient census increases.

On page 40, the applicant states that its proposal is the most effective alternative because it will avoid higher utilization rates and the potential interruptions of patient admissions to the facility.

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

- Adding the four stations will avoid higher utilization rates that can potentially interrupt patient services.
- The applicant provides reasonable information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Bio-Medical Applications of North Carolina, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. Pursuant to Condition 2 of the facility need determination in the 2021 SMFP, the certificate holder shall develop no more than four additional in-center dialysis stations for a total of no more than 54 in-center stations at Fresenius Medical Care Dialysis Services North Ramsey upon completion of this project and Project ID# M-11776-19 (add 10 in-center stations).**

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 fourth month. The first progress report shall be due on May 1, 2022. The second progress report shall be due on September 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 four dialysis stations to FMC Dialysis Services North Ramsey facility pursuant to Condition 2 of the facility need methodology for a total of no more than 54 in-center (IC) dialysis stations upon completion of this project and Project ID# M-11776-19 (add 10 stations).

Capital and Working Capital Costs

In Section Q, page 85, the applicant projects the total capital cost of the project, as shown in the table below.

FMC Dialysis Services North Ramsey Capital Costs	
Non-Medical Equipment	\$3,000
Furniture	\$12,000
Total	\$15,000

In Section Q, page 85, 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. The applicant based the capital cost on what is required

to add the four additional stations. The applicant states that this includes water connection per station, patient chairs, and patient TVs.

In Section F, page 43, the applicant states that there will be no start-up or initial operating expenses associated with the proposed project for an existing facility.

Availability of Funds

In Section F, page 41, 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.	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$15,000	\$15,000
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$15,000	\$ 15,000

* OE = Owner's Equity

Exhibit F-2 contains a letter dated July 15, 2021, from the 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 letter states that in their 2020 Consolidated Balance Sheets, Fresenius Medical Care Holdings, Inc. had over \$446 million in cash and over \$25 billion in assets to fund the capital cost of the proposed project.

Financial Feasibility

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

FMC Dialysis Services North Ramsey	1 st FFY CY 2023	2 nd FFY CY 2024
Total Treatments	24,919	26,169
Total Gross Revenues (Charges)	\$156,767,082	\$164,628,478
Total Net Revenue	\$6,263,842	\$6,577,955
Average Net Revenue per Treatment	\$251	\$251
Total Operating Expenses (Costs)	\$4,937,691	\$5,106,946
Average Operating Expense per Treatment	\$198	\$195
Net Income	\$1,326,151	\$1,471,009

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

- The applicant's provides reasonable assumptions in determining revenue and operating expenses in preparation of Form F.2, F.3 and F.4.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
 - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
 - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to add no more than four dialysis stations to FMC Dialysis Services North Ramsey facility pursuant to Condition 2 of the facility need methodology for a total of no more than 54 in-center (IC) dialysis stations upon completion of this project and Project ID# M-11776-19 (add 10 stations).

On page 113, the 2021 SMFP defines the service area for dialysis stations as "*the service area is the county in which the dialysis station is located*". Thus, the service area for this facility consists of Cumberland County. Facilities may also serve residents of counties not included in their service area.

The table below lists the existing and approved facilities, certified stations, and utilization of dialysis facilities in Cumberland County as of December 31, 2019. There are five kidney disease treatment centers providing dialysis services in Cumberland County.

Facility Name	Certified Stations as of 12/31/2019	# IC Patients as of 12/31/2019	Utilization by Percent as of 12/31/2019	Patients Per Station Per Week
Fayetteville Kidney Center	56	175	78.13%	3.1250
FMC Dialysis Services North Ramsey	40	153	95.63%	3.8250
FMC Dialysis Services South Ramsey	51	167	81.86%	3.2745
FMC Services of West Fayetteville	40	170	106.25%	4.2500
Fresenius Kidney Care Rockfish	0	0		
Total	187	665		

Source: 2021 SMFP, Table 9A, page 121

In Section G, page 48, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Cumberland County. The applicant states:

“This is an application based upon the facility performance and demonstrated need at FMC Dialysis Services North Ramsey. The need addressed by this application is not specific to Cumberland 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:

- The applicant adequately demonstrates that the proposed dialysis stations are needed in addition to the existing or approved dialysis station.
- There is a facility need determination in the 2021 SMFP for the proposed four dialysis stations.

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.

The applicant proposes to add no more than four dialysis stations to FMC Dialysis Services North Ramsey facility pursuant to Condition 2 of the facility need methodology for a total of no more than 54 in-center (IC) dialysis stations upon completion of this project and Project ID# M-11776-19 (add 10 stations).

In Section Q, page 95, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Current FTE Staff	Projected FTE Staff
		2nd Full Fiscal Year CY 2024
Administrator (FMC Clinic Manager)	1.00	1.00
Registered Nurses (RNs)	3.00	5.00
Technicians (PCT)	6.00	12.00
Dietician	0.50	0.50
Social Worker	0.50	0.50
Maintenance	0.50	0.50
Administration/Business Office	1.00	1.00
Other: Director of Operations	0.15	0.15
Other: Chief Technician	0.25	0.25
Other: FMC In-Service	0.25	0.25
TOTAL	13.15	21.15

The assumptions and methodology used to project staffing are provided in Section Q, page 96. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.4. In Section H, pages 50-51, 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:

- FMC Dialysis Services North Ramsey is an existing facility in Cumberland County that has demonstrated its ability to attract qualified staff. The facility offers competitive salaries and a wide range of personnel benefits.
- New employees are required to complete a 10-week training program that includes safety precautions in addition to clinical training.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to add no more than four dialysis stations to FMC Dialysis Services North Ramsey facility pursuant to Condition 2 of the facility need methodology for a total of no more than 54 in-center (IC) dialysis stations upon completion of this project and Project ID# M-11776-19 (add 10 stations).

Ancillary and Support Services

In Section I, page 52, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 52-57, 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 facility has a history of providing the stated ancillary and support services through their existing providers.
- FMC Dialysis Services North Ramsey is an established facility with informal working relationships with other physicians in the area and has agreements in place for lab services, hospital affiliation agreement and a transplant agreement.

Coordination

In Section I, page 57, the applicant describes its existing and proposed relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on its established relationships with other physicians in the area and its agreements for lab services, hospital affiliation agreement and transplant agreement.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

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

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

NA

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

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

NA

The applicant does not propose to construct any new space or renovate any existing space. In Section K, page 60, the applicant states that Project ID# M-11776-19 was approved to add 10

stations to FMC Dialysis Services North Ramsey, which consist of adding physical space to accommodate the additional stations. The proposed four stations will be added to this 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 65, the applicant provides the historical payor mix during CY 2020 for the proposed services, as shown in the table below.

FMC Dialysis Services North Ramsey Historical Payor Mix CY 2020		
Payor Category	# of IC Patients	% of Total IC Patients
Self-Pay	0.5	0.3%
Insurance*	4.1	2.7%
Medicare*	134.6	88.5%
Medicaid*	7.9	5.2%
Other: Misc. Incl. VA	4.9	3.2%
Total	152	100.0%

*Including managed care plans.

In Section L, page 66, the applicant provides the following comparison.

FMC Dialysis Services North Ramsey	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	62.0%	50.4%
Male	38.0%	49.6%
Unknown		
64 and Younger	39.7%	87.8%
65 and Older	60.3%	12.2%
American Indian	0.0%	1.9%
Asian	0.8%	2.7%
Black or African-American	91.7%	39.1%
Native Hawaiian or Pacific Islander	0.0%	0.4%
White or Caucasian	4.1%	42.4%
Other Race	3.3%	13.5%
Declined / Unavailable	0.0%	

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

The Agency reviewed the:

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

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

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 67, the applicant states:

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

In Section L, page 67, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 68, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

FMC Dialysis Services North Ramsey Projected Payor Mix 2nd FFY, CY 2024		
Payor Category	# of IC Patients	% of Total IC Patients
Self-Pay	0.6	0.3%
Insurance*	4.6	2.7%
Medicare*	152.7	88.5%
Medicaid*	9.0	5.2%
Other: Misc. Incl. VA	5.6	3.2%
Total	172.5	100.0%

*Including managed care plans.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 0.6% of total services will be provided to self-pay patients, 88.5% to Medicare patients and 5.2% to Medicaid patients.

In Section L, page 69, the applicant states that the facility does not provide medically indigent and low income patients at no cost to the patient. However, the facility's social worker and business office staff will assist the patient by identifying available sources of funding and completing the required information necessary to obtain assistance.

On page 68, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the

project. The projected payor mix is reasonable and adequately supported based on the following:

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

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 70, 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 four dialysis stations to FMC Dialysis Services North Ramsey facility pursuant to Condition 2 of the facility need methodology for a total of no more than 54 in-center (IC) dialysis stations upon completion of this project and Project ID# M-11776-19 (add 10 stations).

In Section M, page 71, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-1. The applicant adequately demonstrates that health professional

training programs in the area have access to the facility for training purposes based on the following:

- The facility has a history of allowing health-related education and training programs visit the facility to observe the operation of the unit while patients receive treatment.
- The applicant provides a copy of a letter sent to Fayetteville Technical Community College encouraging the school to include FMC Dialysis Services North Ramsey facility in their clinical rotations for nursing students.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to add no more than four dialysis stations to FMC Dialysis Services North Ramsey facility pursuant to Condition 2 of the facility need methodology for a total of no more than 54 in-center (IC) dialysis stations upon completion of this project and Project ID# M-11776-19 (add 10 stations).

On page 113, the 2021 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located*.” Thus, the service area for this facility consists of Cumberland County. Facilities may also serve residents of counties not included in their service area.

The table below lists the existing and approved facilities, certified stations, and utilization of dialysis facilities in Cumberland County as of December 31, 2019. There are five kidney disease treatment centers providing dialysis services in Cumberland County.

Facility Name	Certified Stations as of 12/31/2019	# IC Patients as of 12/31/2019	Utilization by Percent as of 12/31/2019	Patients Per Station Per Week
Fayetteville Kidney Center	56	175	78.13%	3.1250
FMC Dialysis Services North Ramsey	40	153	95.63%	3.8250
FMC Dialysis Services South Ramsey	51	167	81.86%	3.2745
FMC Services of West Fayetteville	40	170	106.25%	4.2500
Fresenius Kidney Care Rockfish	0	0		
Total	187	665		

Source: 2021 SMFP, Table 9A, page 121

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 72, the applicant states:

“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 and projects growth of that population consistent with the Cumberland County Five Year Average Annual Change Rate published in the 2021 SMFP.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 73, 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, C, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 73, the applicant states:

“Fresenius Medical Care, parent organization for this facility, expects every facility to provide high quality care to every patient at every treatment.”

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 73, the applicant states:

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

See also Section 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 adequately demonstrates that:

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

Conclusion

The Agency reviewed the:

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

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

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

C

In Section O, pages 97-101, the applicant identifies the Kidney Treatment Centers located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 126 of this type of facility located in North Carolina.

In Section O, page 78, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to immediate jeopardy has not occurred in any of these facilities. After reviewing and considering information provided by the applicant,

the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

G.S. 131E-183 (b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

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

10A NCAC 14C .2203 PERFORMANCE STANDARDS

- (a) *An applicant proposing to establish a new kidney disease treatment center or dialysis facility shall document the need for at least 10 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, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*
- NA- The applicant does not propose to establish a new kidney disease treatment center or dialysis facility. Therefore, this performance standard is not applicable to this review.
- (b) *An applicant proposing to increase the number of dialysis stations in:*
- (1) *an existing dialysis facility; or*
 - (2) *a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need; shall document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the additional stations.*
- C- In Section C, page 26 and Section Q, page 83, the applicant projects that FMC Dialysis Services North Ramsey will serve 172.5 in-center patients on 54 stations, or a rate of 3.19 patients per station per week, as of the end of the first operating year following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

- (c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section C, pages 26-27, and Section Q, pages 82-83, 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.