

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: February 14, 2020

Findings Date: February 14, 2020

Project Analyst: Tanya M. Saporito

Assistant Chief: Lisa Pittman

Project ID #: M-11776-19

Facility: FMC Dialysis Services North Ramsey

FID #: 960411

County: Cumberland

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

Project: Add no more than 10 dialysis stations for a total of no more than 50 stations upon completion of this project, Project ID #M-11397-17 (add 5 stations) and Project ID #M-11344-17 (relocate 5 stations to FKC Rockfish)

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications of North Carolina, Inc. (hereinafter referred to as “the applicant” or BMA) proposes to add ten dialysis stations to FMC Dialysis Services North Ramsey (FMC North Ramsey), an existing dialysis facility in Fayetteville, for a total of 50 dialysis stations upon completion of this project and the following two projects:

- Project ID #M-11397-17 – Add five dialysis stations to FMC North Ramsey.
- Project ID #M-11344-17 – Relocate five dialysis stations to FKC Rockfish.

Project ID #M-11397-17 was still under development when this application was submitted; therefore, this application was filed as a Change of Scope application, even though it is an application to add additional dialysis stations to FMC North Ramsey pursuant to the Facility Need Determination. Project ID #M-11397-17 was complete as of January 6, 2020.

**Need Determination**

The 2019 State Medical Facilities Plan (2019 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table D, page 62, in the July 2019 Semiannual Dialysis Report (SDR), there is a deficit of six stations in Cumberland County; therefore, there is no 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 based on the facility need methodology if the utilization rate for that dialysis facility, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. The utilization rate reported for FMC North Ramsey in the July 2019 SDR is 3.87 patients per station per week, or 96.88%, based on 155 in-center dialysis patients and 40 certified dialysis stations [ $155 / 40 = 3.87$ ;  $3.87 / 4 = 0.9688$ ]. Therefore, FMC North Ramsey is eligible to apply for additional stations based on the facility need methodology.

Application of the facility need methodology indicates that 30 additional stations are needed at this facility, as illustrated in the following the table, from Section B, page 10:

<b>FMC North Ramsey</b>		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/18		96.9%
Certified Stations		40
Pending Stations		5
<b>Total Existing and Pending Stations</b>		<b>45</b>
In-Center Patients as of 12/31/18 (July 2019 SDR) (SDR2)		155
In-Center Patients as of 6/30/18 (Jan 2019 SDR) (SDR1)		122
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	33
	Multiply the difference by 2 for the projected net in-center change	66
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/18	0.5410
(ii)	Divide the result of Step (i) by 12	0.0451
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/17 until 12/31/18)	0.5410
(iv)	Multiply the result of Step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	238.8525
(v)	Divide the result of Step (iv) by 3.2 patients per station	74.6414
	and subtract the number of certified and pending stations to determine the number of stations needed	29.6414

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed at FMC North Ramsey is 30, based on rounding allowed in Step (v). Step (C) of the facility need methodology states, “*The facility may apply to expand*

*to meet the need established ..., up to a maximum of ten stations.”* The applicant proposes to add ten new stations; therefore, the application is consistent with the facility need determination for dialysis stations.

### **Policies**

*Policy GEN-3: Basic Principles and Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities* are applicable to this review.

Policy GEN-3, on page 31 of the 2019 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.3 (a and d), pages 12 and 14 - 15, respectively; Sections N.1 and N.2(b), pages 55 - 56; Section O, pages 58 - 61; 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.3, pages 12 - 13; Section N.2(c), page 56; 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.3, pages 13 - 14; Sections N.1 and N.2(a), pages 55 - 56; and referenced exhibits. The information provided by the applicant with regard to its efforts to maximize healthcare value 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.

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, on page 31 of the 2019 SMFP, states:

*“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.*

*In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4.*

*Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan of energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control.”*

The proposed capital expenditure for this project is greater than \$2 million and less than \$5 million; therefore, Policy GEN-4 is applicable to this review. In Section B.4, pages 15 - 16, the applicant provides a written commitment assuring improved energy efficiency and water conservation in its construction project. The applicant states that renovations will be performed using the latest technologies to assure maximum energy efficiency.

In Section K, pages 45 - 46, the applicant explains the strategies to be incorporated as energy saving features into the renovation plans. The applicant adequately demonstrates that the application includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation. The application is consistent with Policy GEN-4.

## **Conclusion**

The Agency reviewed the:

- application,

- exhibits to the application, and
- information publicly available during the review and used by the Agency.

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

- (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, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

## C

Bio-Medical Applications of North Carolina, Inc. (hereinafter referred to as “the applicant” or BMA) proposes to add ten dialysis stations to FMC Dialysis Services North Ramsey (FMC North Ramsey), an existing dialysis facility in Fayetteville, for a total of 50 dialysis stations upon completion of this project and the following two projects:

- Project ID #M-11397-17 – Add five dialysis stations to FMC North Ramsey.
- Project ID #M-11344-17 – Relocate five dialysis stations to FKC Rockfish.

Project ID #M-11397-17 was under development when this application was submitted; therefore, this application was filed as a Change of Scope application, even though it is an application to add additional dialysis stations to FMC North Ramsey pursuant to the Facility Need Determination. Project ID #M-11397-17 was complete as of January 6, 2020.

### **Patient Origin**

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area for this facility is Cumberland County. Facilities may serve residents of counties not included in their service area.

In Section C.2, page 18, the applicant provides historical patient origin for FMC North Ramsey in-center (IC) patients for calendar year (CY) 2018, as illustrated in the table below:

**FMC North Ramsey Historical Patient Origin  
January 1, 2018 – December 31, 2018**

COUNTY	# IN-CENTER PTS.	% OF TOTAL
Cumberland	146	94.19%
Harnett	7	4.52%
Other States	2	1.29%
<b>Total</b>	<b>155</b>	<b>100.00%</b>

Totals may not sum due to rounding

The applicant projects patient origin for the second full year of operation, CY 2022 in Section C, page 18, as illustrated in the following table:

**FMC North Ramsey Projected Patient Origin  
January 1, 2022 – December 31, 2022**

COUNTY	# IN-CENTER PTS.	% OF TOTAL
Cumberland	167.6	95.44%
Harnett	8.0	4.56%
<b>Total</b>	<b>175.6</b>	<b>100.00%</b>

Totals may not sum due to rounding

In Section C, pages 19 - 20, the applicant provides the assumptions and methodology it used to project patient origin. The applicant's assumptions are reasonable and adequately supported.

**Analysis of Need**

In Section C.4, page 21 the applicant states that the need the proposed population has for the proposed services is a function of the individual patient need for dialysis care and treatment. In addition, the applicant states that dialysis treatment is necessary for patients with End Stage Renal Disease.

In Section C, pages 19 - 20 and Section Q, pages 70 - 71, the applicant provides the assumptions and methodology for projecting in-center patient utilization, summarized as follows:

- The applicant provides a table on pages 19 and 70 that shows the facility in-center census as of December 31, 2018 and June 30, 2019, as summarized below.

**FMC NORTH RAMSEY  
IN-CENTER PATIENTS**

COUNTY	12/31/2018	6/30/2019
Cumberland	146	148
Harnett	7	5
Other States	2	0
<b>Total</b>	<b>155</b>	<b>156</b>

- The applicant states that it will begin its analysis with the facility patient census as of June 30, 2019, which was submitted to the Agency on the ESRD Data Collection form in August 2019 and is shown in the table above.
- The applicant projects growth of the Cumberland County patient population based on the 4.6% Cumberland County Five Year Average Annual Change Rate (AACR) published in the July 2019 SDR.
- The applicant has three other pending projects which are impacted by or which impact this project, as follows:
  - Project ID #M-11286-17 – application to develop a new 10-station dialysis facility. The applicant projected one patient would transfer their care from FMC North Ramsey.
  - Project ID #M-11344-17 – application to develop a new 10-station dialysis facility. The applicant projected that four patients would transfer their care from FMC North Ramsey.
  - Project ID #M-11502-18 – Change of scope application that combined the two previous applications into a new 20-station dialysis facility, Fresenius Kidney Care Rockfish. The applicant maintained the transfer of five patients pursuant to the two applications that merged.
- The applicant projects project completion by December 31, 2021. Therefore, Operating Year (OY) 1 is calendar year (CY) 2022, January 1 - December 31, 2022 and OY 2 is CY 2023, January 1 - December 31, 2023.

*Projected Utilization*

In Section C, page 20 and Section Q, page 71, the applicant provides the methodology it used to project utilization, based on its stated assumptions, as illustrated in the following table:

<b>FMC NORTH RAMSEY IN-CENTER PATIENTS</b>	
Begin with Cumberland County patient population as of June 30, 2019.	148
Project forward six months to December 31, 2019 using one-half of the Cumberland County Five Year AACR in the July 2019 SDR of 4.6%.	$148 \times 1.023 = 151.4$
Subtract five Cumberland County patients projected to transfer to FKC Rockfish	$151.4 - 5 = 146.4$
Add the Harnett County patients dialyzing at the facility	$146.4 + 8 = 154.4$
Project Cumberland County patient population forward one year to December 31, 2020 using Cumberland County Five Year AACR of 4.6%.	$146.4 \times 1.046 = 153.1$
Project Cumberland County patient population forward one year to December 31, 2021 using Cumberland County Five Year AACR of 4.6%.	$153.1 \times 1.046 = 160.2$
Add the Harnett County patients dialyzing at the facility This is the beginning census for the project.	$160.2 + 8 = 168.2$
Project Cumberland County patient population forward one year to December 31, 2022 using Cumberland County Five Year AACR of 4.6%.	$160.2 \times 1.046 = 167.6$
Add the Harnett County patients dialyzing at the facility This is the ending census for OY 1 of the project.	$167.6 + 8 = 175.6$
Project Cumberland County patient population forward one year to December 31, 2023 using Cumberland County Five Year AACR of 4.6%.	$167.6 \times 1.046 = 175.3$
Add the Harnett County patients dialyzing at the facility This is the ending census for OY 2 of the project.	$175.3 + 8 = 183.3$

Source: Tables in Sections C and Q, pages 20 and 71, respectively.

At the end of OY 1 (CY 2022), FMC North Ramsey projects to serve 175.6 in-center patients on 50 stations, for a utilization rate of 87.8%; and at the end of OY 2 (CY 2022) the facility is projected to serve 183.3 in-center patients on 50 stations, for a utilization rate of 91.7%.

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

- OY 1: 3.51 patients per station per week, or 87.8% utilization:  $175.6 \text{ patients} / 50 \text{ stations} = 3.51$ ;  $3.51 / 4 = 0.878$ .
- OY 2: 3.67 patients per station per week, or 91.7% utilization:  $183.3 \text{ patients} / 50 \text{ stations} = 3.67$ ;  $3.67 / 4 = 0.917$ .

The projected utilization of 3.5 patients per station per week at the end of OY 1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

Projected utilization is reasonable and adequately supported for the following reasons:



- FMC North Ramsey was operating at 96.88% of capacity as of December 31, 2018, as reported in the July 2019 SDR.
- The applicant projects future in-center patient utilization based on historical utilization.
- The applicant projects growth of the Cumberland County in-center patient population using the Cumberland County AACR of 4.6%.
- Projected in-center utilization at the end of OY 1 exceeds the minimum of 3.2 patients per station per week required by 10A NCAC 14C .2203(b).

**Access**

In Section C.7, pages 22 - 23, the applicant states:

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

...

*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.”*

In Section L, page 51, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as summarized in the following table.

**FMC North Ramsey Projected Payor Mix, CY 2023**

<b>PAYOR SOURCE</b>	<b>% OF TOTAL</b>
Self Pay	0.35%
Insurance*	2.64%
Medicare*	68.61%
Medicaid*	7.68%
Medicare Commercial	16.47%
Miscellaneous (Incl. VA)	4.25%
<b>Total</b>	<b>100.00%</b>

\*Includes any managed care plans

Totals may not sum due to rounding

The applicant indicated that the second OY is CY 2022; however, the Project Analyst determined, based on the information in the application, that it is a typographical error.

The projected payor mix is reasonable and adequately supported.

## **Conclusion**

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

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

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payer mix) and adequately supports its assumptions.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, 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 ten dialysis stations to FMC North Ramsey, an existing dialysis facility, for a total of 50 dialysis stations upon completion of this project and the following two projects:

- Project ID #M-11397-17 – Add five dialysis stations to FMC North Ramsey.
- Project ID #M-11344-17 – Relocate five dialysis stations to FKC Rockfish.

Project ID #M-11397-17 was under development when this application was submitted; therefore, this application was filed as a Change of Scope application, even though it is an

application to add additional dialysis stations to FMC North Ramsey pursuant to the Facility Need Determination. Project ID #M-11397-17 was complete as of January 6, 2020.

In Section E, pages 29 - 30, the applicant states it considered the following alternatives related to serving the needs of the dialysis patients in the service area:

1. Maintain the status quo – the applicant states this was not a reasonable alternative because it fails to recognize the growth of the ESRD patient population residing in the service area of FMC North Ramsey. The applicant states the facility is well-utilized, and projects to serve 183.3 in-center patients at the end of OY 2.
2. Apply for fewer than ten stations – the applicant states this is not a reasonable alternative because it would result in having to file another application for facility expansion because of the high utilization rate.
3. Relocate stations from another BMA facility in Cumberland County – the applicant states it considered relocating stations from one of its other dialysis facilities in Cumberland County, as follows:
  - a. Fayetteville Kidney Center – the applicant states this facility was operating at 84.5% as reported in the July 2019 SDR. Relocating stations from this facility would not be appropriate.
  - b. FMC Services of West Fayetteville – the applicant states utilization at this facility was 110.63% at the end of 2018. The applicant was awarded a certificate of need, effective December 10, 2019 to add four stations to that facility. Relocating stations from this facility would not be appropriate.
  - c. FMC Dialysis Services South Ramsey – the applicant states utilization at this facility was 72.06% as reported in the July 2019 SDR. The applicant states the facility is utilized by transient patients, and there are two other pending projects that impact the stations at the facility. Relocating stations from this facility would not be appropriate.

On page 30, the applicant states that it elected to add ten stations pursuant to the facility need determination because this proposal is the most cost-effective approach to providing the necessary services for the patient population projected to be served at FMC North Ramsey.

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

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provided 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, and
- information publicly available during the review and used by the Agency.

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

- 1. Bio-Medical Applications of North Carolina, Inc. shall materially comply with all representations made in the certificate of need application.**
  - 2. Pursuant to the facility need determination in the July 2019 SDR, Bio-Medical Applications of North Carolina, Inc. shall develop no more than ten additional dialysis stations at FMC Dialysis Services North Ramsey for a total of no more than 50 dialysis stations, which shall include any home hemodialysis training or isolation stations, upon completion of this project, Project ID #M-11397-17 (add five stations) and Project ID #M-11344-17 (relocate five stations to FKC Rockfish).**
  - 3. Bio-Medical Applications of North Carolina, Inc. 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 ten dialysis stations to FMC North Ramsey, an existing dialysis facility, for a total of 50 dialysis stations upon completion of this project and two additional projects.

**Capital and Working Capital Costs**

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

Construction/Renovation	\$1,422,757
Architect / Engineering Fees	\$ 99,593
Non-Medical Equipment	\$ 364,787
Furniture	\$ 33,690
Contingency	\$ 228,352
<b>Total</b>	<b>\$2,149,179</b>

In Section Q, page 74, the applicant provides the assumptions used to project the capital cost.

In Section F.3, page 32, 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 currently operational.

**Availability of Funds**

In Section F.2, page 31, 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 *	\$2,149,179	\$2,149,179
Bonds	0	0
Other (Specify)	0	0
<b>Total Financing</b>	<b>\$2,149,179</b>	<b>\$2,149,179</b>

\* OE = Owner's Equity

Exhibit F-2 contains a letter dated September 16, 2019 from the Senior Vice President and Treasurer, authorizing and committing accumulated reserves of Fresenius Medical Care Holdings, Inc. (FMCH), the parent company for BMA, for the capital costs of the project. The letter also documents that the 2018 Consolidated Balance Sheet for FMCH reflects more than \$1.8 billion in cash, and total assets exceeding \$20 billion.

**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 of the project, as summarized in the table below.

FMC NORTH RAMSEY PROJECTED REVENUE AND OPERATING EXPENSES		
	OY 1 CY 2022	OY 2 CY 2023
Total Treatments	25,436.34	26,551.95
Total Gross Revenue (charges)	\$160,020,019	\$167,038,307
Total Net Revenue	\$6,096,801	\$6,364,199
Average Net Revenue per Treatment	\$239.68	\$239.68
Total Operating Expenses (costs)	\$5,899,723	\$6,089,034
Average Operating Expense per Treatment	\$231.94	\$229.33
<b>Net Income / Profit (loss)</b>	<b>\$197,078</b>	<b>\$275,165</b>

Totals may not sum due to rounding by Project Analyst

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs, and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

### **Conclusion**

The Agency reviewed the:

- application, and
- 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 ten dialysis stations to FMC North Ramsey, an existing dialysis facility, for a total of 50 dialysis stations upon completion of this project and the following two projects:

- Project ID #M-11397-17 – Add five dialysis stations to FMC North Ramsey. This project was complete as of January 6, 2020.
- Project ID #M-11344-17 – Relocate five dialysis stations to FKC Rockfish.

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” The facility is located in Cumberland County; thus, the service area for this facility consists of Cumberland County. Facilities may also serve residents of counties not included in their service area.

According to the July 2019 SDR, there are five existing and approved dialysis facilities in Cumberland County, all of which are owned or operated by the applicant or a related entity, as follows:

**Cumberland County Dialysis Facilities, July 2019 SDR (as of 12/31/18)**

FACILITY	# IN-CENTER PATIENTS	# STATIONS	% UTILIZATION
Fayetteville Kidney Center	169	50	84.50%
FMC Dialysis Services North Ramsey	155	40	96.88%
FMC Dialysis Services South Ramsey	147	51	72.06%
FMC Dialysis Services of West Fayetteville	177	40	110.63%
Fresenius Kidney Care Rockfish	0	0	0.00%
<b>Total</b>	<b>648</b>	<b>181</b>	

On page 36, the applicant also provides a table to illustrate the number of dialysis stations and in-center patients in Cumberland County as of June 30, 2019, as shown below:

**Cumberland County Dialysis Facilities as of June 30 19, 2019**

FACILITY	# IN-CENTER PATIENTS	# STATIONS	% UTILIZATION
Fayetteville Kidney Center	166	56	74.11%
FMC Dialysis Services North Ramsey	156	40	97.50%
FMC Dialysis Services South Ramsey	157	51	76.96%
FMC Dialysis Services of West Fayetteville	181	40	113.13%
Fresenius Kidney Care Rockfish	0	0	0.00%
<b>Total</b>	<b>660</b>	<b>187</b>	

Source: application page 36, using data from the ESRD Data Collection Forms submitted to the Agency

Per the July 2019 SDR, as of December 31, 2018, Fresenius related entities own and operate all of the existing dialysis facilities in Cumberland County with a total of 181 certified stations. As stated in Section G, page 36, utilization in three of the existing Cumberland County facilities increased as of June 30, 2019, as shown on the August 2019 ESRD Data Collection Forms.

In Section G, page 37, the applicant explains why it believes the proposal would not result in the unnecessary duplication of existing or approved dialysis services in Cumberland County based on the utilization as of June 30, 2019. The applicant states:

*“This is an application to add ten stations to FMC North Ramsey. All of the BMA facilities in Cumberland County are well utilized. The overall utilization by 660 dialysis patients on 187 certified dialysis stations is 3.5294 patients per station.*

*BMA is not proposing to duplicate services, but to ensure a sufficient number of stations remain available for the patients of the area. The July 2019 SDR reports a deficit of six stations for Cumberland County. Adding stations will not duplicate services.”*

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

- There is a facility need determination for up to 29 additional dialysis stations at FMC North Ramsey, as calculated using the facility need methodology in the July 2019 SDR.
- The applicant does not propose to develop more dialysis stations than are shown to be needed in the service area.
- The applicant adequately demonstrates that the proposed dialysis stations are needed in addition to the existing or approved additional dialysis stations.

**Conclusion**

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

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

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

C

In Form H Staffing, in Section Q, page 84, the applicant provides a table illustrating current and projected OY 2 staffing in full time equivalents (FTEs) for FMC North Ramsey, as summarized below.

**FMC North Ramsey Current and Projected Staffing**

POSITION	FTE POSITIONS AS OF 6/30/19	FTE POSITIONS OY 1 (CY 2022)	FTE POSITIONS OY 2 (CY 2023)
FMC Clinic Manager	1.00	1.00	1.00
Registered Nurses	7.00	8.50	8.50
LPNs	1.00	1.00	1.00
Technicians	11.00	13.00	13.00
Dietician	1.00	1.50	1.50
Social Worker	1.00	1.50	1.50
Equipment Technician	1.00	1.00	1.00
Administration/Business Office	2.00	2.00	2.00
FMC Director of Operations	0.20	0.20	0.20
In-Service	0.30	0.30	0.30
Chief Technician	0.15	0.15	0.15
<b>Total</b>	<b>25.65</b>	<b>30.15</b>	<b>30.15</b>

Source: Section Q Form H



The applicant projects to hire 1.5 new registered nurse FTE positions, two technician FTE positions and 0.5 dietician FTE positions following the addition of ten stations as proposed in this application. Adequate costs for the current health manpower and management positions are budgeted in Form F.4 Operating Costs. In Section H, page 39, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. Exhibit H contains documentation of its continuing education programs. In Section H.4, page 40, the applicant identifies the current medical director for the facility as Dr. Mittal. In Exhibit H-4, the applicant provides a letter from Dr. Mittal confirming his intent to continue to serve as medical director for the proposed services.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

### **Conclusion**

The Agency reviewed the:

- application, and
- 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.

### C

In Section I, page 42, the applicant states that the following ancillary and support services are necessary for the proposed services, and explains how each ancillary and support service is made available:

JOHNSTON DIALYSIS ANCILLARY AND SUPPORT SERVICES	
SERVICES	PROVIDER
Self-care training	Referred to Fayetteville Kidney Center
Home training Home Hemodialysis Peritoneal Dialysis Accessible follow-up program	Referred to Fayetteville Kidney Center
Psychological counseling	Referral to Fayetteville Psychiatric
Isolation – hepatitis	Provided on site by applicant
Nutritional counseling	Provided on site by applicant
Social Work services	Provided on site by applicant
Acute dialysis in an acute care setting	Cape Fear Valley Hospital
Emergency care	Provided by facility staff until ambulance arrives
Blood bank services	Cape Fear Valley Hospital
Diagnostic and evaluation services	Cape Fear Valley Hospital, Valley Regional Imaging
X-ray services	Cape Fear Valley Hospital, Valley Regional Imaging
Laboratory services	Provided on site by applicant
Pediatric nephrology	Referral to UNC Healthcare
Vascular surgery	Referral to Sandhills Surgical Assoc., Harnett Surgical, Pinehurst Surgical, Triangle Vascular
Transplantation services	Referral to UNC Healthcare
Vocational rehabilitation & Counseling	NC Division of Vocational Rehab, Fayetteville
Transportation	B & W Transportation, FAST, Cumberland County Medicaid Transportation

Source: Application page 42

In Section I, page 42, the applicant describes its existing and proposed relationships with other local health care and social service providers. In Exhibit I, the applicant provides supporting documentation for established relationships with local health care providers and for referrals.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

**Conclusion**

The Agency reviewed the:

- application, and
- exhibits to the application.

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

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

NA

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

C

The applicant proposes to add ten dialysis stations to FMC North Ramsey for a total of 50 dialysis stations upon completion of this project and Project ID#M-11344-17. Project ID #M-11397-17 was complete as of January 6, 2020.

In Section K, page 45, the applicant states that the project proposes to construct 3,500 square feet of new space. In addition, the applicant states that Fresenius Medical Care Real Estate and Construction Services team will design the facility for energy efficiency. Line drawings are provided in Exhibit K.1.

On page 46, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal, and why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

On page 46, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

### **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.

(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 handicapped persons, 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 50, the applicant provides the historical payor mix during the last full operating year at FMC North Ramsey as summarized in the table below.

**FMC NORTH RAMSEY  
HISTORICAL PAYOR MIX CY 2018**

PAYOR SOURCE	% OF TOTAL PATIENTS
Self pay	0.35%
Insurance*	2.64%
Medicare*	68.61%
Medicaid*	7.68%
Medicare Commercial	16.47%
Other (VA)	4.25%
<b>Total</b>	<b>100.00%</b>

Numbers may not sum due to rounding

In Section L.1(a), page 49, the applicant compares demographic information on FMC Dialysis Services of North Ramsey patients and the service area population during the last full operating year, as summarized below:

	PERCENTAGE OF TOTAL JOHNSTON DIALYSIS PATIENTS SERVED DURING THE LAST FULL OY	PERCENTAGE OF THE POPULATION OF THE SERVICE AREA
Female	43.5%	52.3%
Male	56.5%	47.7%
Unknown		
64 and Younger	54.0%	86.9%
65 and Older	46.0%	13.1%
American Indian	0.0%	0.9%
Asian	0.6%	5.5%
Black or African-American	79.5%	37.3%
Native Hawaiian or Pacific Islander	0.6%	0.1%
White or Caucasian	11.8%	53.7%
Other Race	0.6%	2.5%
Declined / Unavailable	6.2%	

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

**Conclusion**

The Agency reviewed the:

- application,
- exhibits to the application, and
- information 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 handicapped persons 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, the applicant states in Section L, page 50, that it has no obligation in any of its facilities to provide uncompensated care,

community service, or access by minorities or handicapped persons under any federal regulations.

In Section L, page 51, the applicant states that during the last five years 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.

**Conclusion**

The Agency reviewed the:

- application, and
- 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 51, the applicant projects the following payor mix for the proposed services during the second full operating year following completion of the project, as summarized in the table below.

**FMC NORTH RAMSEY  
PROJECTED PAYOR MIX CY 2023**

<b>PAYOR SOURCE</b>	<b>% OF TOTAL</b>
Self pay	0.35%
Insurance*	2.64%
Medicare*	68.61%
Medicaid*	7.68%
Medicare Commercial	16.47%
Other (VA)	4.25%
<b>Total</b>	<b>100.00%</b>

Numbers may not sum due to rounding  
The applicant put CY 2022 as a table heading; however, the Project Analyst determined that is a typographical error, because the applicant indicates in Form C and in other sections of the application that the first OY is CY 2022 and OY 2 is CY 2023.

As shown in the table above, during the second year of operation, the applicant projects that 0.35% of total in-center services will be provided to self-pay patients, 85.05% to

Medicare patients (includes Medicare and Medicare/Commercial), and 7.68% to Medicaid patients.

On page 51, the applicant provides the assumptions and methodology it uses to project payor mix during the second full year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because the projected payor mix is based on the historical payor mix of FMC North Ramsey.

### **Conclusion**

The Agency reviewed the:

- application, and
- exhibits to the application.

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

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

C

In Section L, page 52, the applicant adequately describes the range of means by which patients will have access to the proposed services.

### **Conclusion**

The Agency reviewed the:

- application, and
- 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

In Section M, page 54, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-2.

## Conclusion

The Agency reviewed the:

- application, and
- 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 ten dialysis stations to FMC North Ramsey, an existing dialysis facility, for a total of 50 dialysis stations upon completion of this project and the following two projects:

- Project ID #M-11397-17 – Add five dialysis stations to FMC North Ramsey. This project was complete as of January 6, 2020.
- Project ID #M-11344-17 – Relocate five dialysis stations to FKC Rockfish.

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” The facility is located in Cumberland County; thus, the service area for this facility consists of Cumberland County. Facilities may also serve residents of counties not included in their service area.

According to the July 2019 SDR, there are five existing and approved dialysis facilities in Cumberland County, all of which are owned or operated by the applicant or a related entity, as follows:



**Cumberland County Dialysis Facilities, July 2019 SDR (as of 12/31/18)**

FACILITY	# IN-CENTER PATIENTS	# STATIONS	% UTILIZATION
Fayetteville Kidney Center	169	50	84.50%
FMC Dialysis Services North Ramsey	155	40	96.88%
FMC Dialysis Services South Ramsey	147	51	72.06%
FMC Dialysis Services of West Fayetteville	177	40	110.63%
Fresenius Kidney Care Rockfish	0	0	0.00%
<b>Total</b>	<b>648</b>	<b>181</b>	

In Section N, pages 55 - 57, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality, and access to the proposed services. The applicant states:

*“The applicant does not expect this proposal to have any effect on the competitive climate in Cumberland County. The applicant does not project to serve dialysis patients currently being served by another provider. The projected patient population for the facility begins with patients currently dialyzing at the facility.*

*There are currently four operational dialysis facilities within Cumberland County, and FKC Rockfish, which is nearing completion, and planned for certification by year end 2019. With this application; BMA seeks the opportunity to continue providing dialysis care and treatment to the patients of the area of western Cumberland County and patients from eastern Hoke County who desire to dialyze at the facility.*

...

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

...

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

...

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

...

*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.”*

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections B, F, and Q of the application and any exhibits).
- Quality services will be provided (see Sections B and O of the application and any exhibits).
- Access will be provided to underserved groups (see Sections B and L of the application and any exhibits).

### **Conclusion**

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion for 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 A Facilities, the applicant identifies 127 kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity.

In Section O, page 61, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care that resulted in a finding of “*Immediate Jeopardy*” occurred in any of these facilities. 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.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to

demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

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

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

(a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year 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- FMC North Ramsey is an existing facility.

(b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*

-C- In Section C, page 20 and Section Q Form C, page 69, the applicant projects that FMC North Ramsey will serve 175.6 in-center patients on 50 stations, or a rate of 3.51 patients per station per week, as of the end of the first operating year following project completion. This exceeds the minimum performance standard of 3.2 patient per station per week. 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 18 - 20 and Section Q, pages 70 - 71, the applicant provides the assumptions and methodology it used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.