

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: February 18, 2022

Findings Date: February 18, 2022

Project Analyst: Celia C. Inman

Team Leader: Micheala Mitchell

Project ID #: M-12168-21

Facility: FMC Dialysis Services of South Ramsey

FID #: 970530

County: Cumberland

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

Project: Add no more than six dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 56 stations upon completion of this project, Project ID# M-12038-21 (add 9), and Project ID# M-12129-21 (relocate 6)

### 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

The applicant, Bio-Medical Applications of North Carolina, Inc. (BMA), proposes to add no more than six dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 56 stations at FMC Dialysis Services of South Ramsey (FMC South Ramsey) upon completion of this project, Project ID# M-12038-21 (add 9 stations), and Project ID# M-12129-21 (relocate 6 stations from FMC South Ramsey to Fresenius Kidney Care Hope Mills).

## **Need Determination**

Chapter 9 of the 2021 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table 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 75.00% or 3.0 patients per station per week, as stated in Condition 2.a. In Table 9A, page 121, the utilization rate reported for the facility is 81.86% or 3.27 patients per station per week, based on 167 in-center dialysis patients and 51 certified dialysis stations ( $167 \text{ patients} / 51 \text{ stations} = 3.27$ ;  $3.27 / 4 = 0.8186$ ).

As shown in Table 9D, page 138, based on the facility need methodology for dialysis stations, the potential number of stations needed is up to 20 additional stations; thus, the applicant is eligible to apply to add up to 20 stations during the 2021 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

In the April 2021 review cycle, the applicant applied for and was conditionally approved to add nine dialysis stations at FMC South Ramsey pursuant to Condition 2 of the facility need methodology in Project ID #M-12038-21. The applicant now proposes to add no more than six new stations to the facility, which would be a total of no more than 15 dialysis stations added pursuant to Condition 2 in the 2021 SMFP review cycle, which is consistent with the 2021 SMFP calculated facility need determination for up to 20 stations; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

## **Policies**

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

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

## **Promote Safety and Quality**

The applicant describes how it believes the proposed project will promote safety and quality in Section B, page 21; Section N, page 75; Section O, pages 77-80; and referenced exhibits. The

information provided by the applicant is reasonable and supports the determination that the applicant's proposal will promote safety and quality.

### Promote Equitable Access

The applicant describes how it believes the proposed project will promote equitable access in Section B, page 22; Section C, page 31; Section L, pages 67-72; Section N, page 75; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant's proposal will promote equitable access.

### Maximize Healthcare Value

The applicant describes how it believes the proposed project will maximize healthcare value in Section B, pages 22-23; Section N, pages 74-75; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant's proposal will maximize healthcare value.

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

### Conclusion

The Agency reviewed the:

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

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

- The applicant adequately demonstrates that the application is consistent with the facility need methodology as applied from the 2021 SMFP.
- The applicant adequately demonstrates how the facility's projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need.
- The applicant adequately demonstrates that the application is consistent with Policy GEN-3 based on how it describes the facility's policies and programs, which promote the concepts of quality, equitable access and maximum value for resources.

- (2) Repealed effective January 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

The applicant proposes to add no more than six dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 56 stations at FMC South Ramsey upon completion of this project, Project ID# M-12038-21 (add 9), and Project ID# M-12129-21 (relocate 6). Following the submission of the project under review, Project ID #M-12038-21 was completed (as of November 29, 2021) for a total of 56 stations at FMC South Ramsey. Upon completion of Project ID #M-12029-21 to relocate six stations from FMC South Ramsey, FMC South Ramsey will have a total of 50 dialysis stations. Thus, the applicant proposes to add back six stations in existing facility space for a total of 56 stations again.

**Patient Origin**

On page 113, the 2021 SMFP defines the service area for the county need methodology for dialysis stations as *“the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay, and Graham counties and Avery, Mitchell, and Yancey counties.”* FMC South Ramsey is located in Cumberland County. Thus, the service area for this application is Cumberland County. Facilities may serve residents of counties not included in their service area.

In Section C.1, page 25, the applicant provides the historical in-center (IC) patient origin for FMC South Ramsey, as summarized below. The facility does not serve home hemodialysis (HH) or peritoneal dialysis (PD) patients.

**Historical Patient Origin  
(1/1/2020-12/31/2020)**

<b>County</b>	<b>Patients</b>	<b>% of Total</b>
Cumberland	161	98.8%
Hoke	1	0.6%
Robeson	1	0.6%
<b>Total</b>	<b>163</b>	<b>100.0%</b>

Source: Section C.2, page 25

The following table summarizes the projected in-center patient origin at FMC South Ramsey in the second full fiscal year (FY) of operations, calendar year (CY) 2024, as provided on page 26 of the application.

**Second Full FY of Operation following Project Completion  
01/01/2023 to 12/31/2023 [CY2024]**

County	Patients	% of Total
Cumberland	182.8	98.9%
Hoke	1	0.5%
Robeson	1	0.5%
<b>Total</b>	<b>184.8</b>	<b>100.0%</b>

Source: Section C.3, page 26

Note that the applicant incorrectly dated the Second Full FY in its table on page 26.

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

*“BMA is proposing to add six dialysis stations to FMC Dialysis Services South Ramsey for a total of 56 stations upon project completion. The facility will continue to offer in-center dialysis.”*

The applicant’s assumptions are reasonable and adequately supported based on the following:

- The applicant begins with the historical December 31, 2020 patient census.
- The applicant applies the Average Annual Change Rate (AACR) published in the 2021 SMFP, 5.2%, for predicting growth of the Cumberland County patients.
- The applicant assumes the two patients from outside Cumberland County will continue to dialyze at the facility and adds the two patients for future projections, with no growth.
- The proposed new stations are projected to be certified as of December 31, 2022.
- Operating Year (OY) 1, the first full FY is CY2023. OY2 is CY2024.

**Analysis of Need**

In Section C, pages 28-29, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 29, the applicant states:

*“The need that this population has for the proposed services is a function of the individual patient need for dialysis care and treatment. This question specifically addresses the need that the population to be served has for the proposed project. The applicant has identified the population to be served as 175.8 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 78.47%, or 3.14 patients per station and exceeds the minimum required by the performance standard.”*

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

- Page 138 of the 2021 SMFP shows a facility need determination for up to 20 stations at FMC South Ramsey during the 2021 SMFP review cycle.

- The applicant applies the Cumberland County AACR as provided in the 2021 SMFP to project growth in Cumberland County patient utilization.
- The applicant assumes patients from Hoke and Robeson counties will continue to dialyze at the facility but does not project a growth for patients from those counties.

Projected Utilization

In Section Q Form C, page 83, the applicant provides the projected utilization, as summarized in the following table. The facility serves only IC dialysis patients.

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

<b>Form C Utilization</b>	<b>Last Full FY CY2020</b>	<b>Interim FY CY2021</b>	<b>Interim FY CY2022</b>	<b>1st Full FY CY2023</b>	<b>2nd Full FY CY2024</b>
In-Center Patients					
# of Patients at the Beginning of the Year	175	163	171	180	176
# of Patients at the End of the Year	163	171	180	176	185
Average # of IC Patients during the Year	169	167	176	178	108
# of Treatments / Patient / Year	148	148	148	148	148
Total # of Treatments per Application [Total # of Treatments per Analyst Calculations]	23,108 [25,012]	24,744 [24,716]	26,015 [26,048]	26,340 [26,344]	26,682 [26,640]

Based on the applicant’s assumptions and methodology (average # patients during the year (# patients beginning of year + # patients end of year/2) x average # of treatments (148) = total # of treatments), the calculation for average # of patients during the year are actually based on fractions and not the rounded whole numbers that are presented in the table above and the total number of treatments for CY2020 was not calculated correctly based on the number of patients provided in the table.

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

- The first full FY is CY2023, the period from January 1-December 31, 2023
- The second full FY is CY2024
- Projections begin with the facility census as of December 31, 2020
- The applicant grows the Cumberland County patient census by 5.2%, the 5-year AACR as found in the 2021 SMFP, page 133
- The facility also serves two in-center patients residing in Hoke and Robeson counties, which the applicant states are assumed to continue to dialyze at the facility, but the utilization is not projected to grow
- Project M-12129-21 was approved to relocate six dialysis stations and transfer 13 Cumberland County patients from FMC South Ramsey to FKC Hope Mills as of December 31, 2022
- The proposed new stations will be installed and certified as of December 31, 2022

The applicant provides a table in Section C, page 27, and in Section Q, page 85, illustrating the application of its assumptions and methodology, as summarized below. Project ID #M-12038-21 approved the addition of the nine stations at FMC South Ramsey and they were certified as of November 29, 2021 and are included in the total number of stations at FMC South Ramsey upon completion of the project under review.

<b>Projected FMC South Ramsey In-Center Patients</b>	
Begin with the Cumberland County patient population as of December 31, 2020.	161
Project the Cumberland County patient population forward one year to December 31, 2021, using the Five-Year AACR (5.2%).	$161 \times 1.052 = 169.4$
Project the Cumberland County patient population forward one year to December 31, 2022, using the Five-Year AACR (5.2%).	$169.4 \times 1.052 = 178.2$
Subtract 13 Cumberland County patients projected to transfer to FKC Hope Mills. This is the projected Cumberland County patient starting census for this project as of December 31, 2022.	$178.2 - 13 = 165.2$
Project the Cumberland County patient population forward one year to December 31, 2023, using the Five-Year AACR (5.2%).	$165.2 \times 1.052 = 173.8$
Add the two patients from other counties. This is the projected ending census for Operating Year 1, CY2023.	$173.8 + 2 = 175.8$
Project the Cumberland County patient population forward one year to December 31, 2024, using the Five-Year AACR (5.2%).	$173.8 \times 1.052 = 182.8$
Add the two patients from other counties. This is the projected ending census for Operating Year 2, CY2024.	$182.8 + 2 = 184.8$

Totals may not sum due to rounding

As the table above shows, using conventional rounding, the applicant’s methodology achieves a projection of 175.8 in-center patients by the end of the first full FY, OY1 (ending December 31, 2023), for a utilization rate of 3.14 patients per station per week or 78.5% ( $175.8 \text{ patients} / 56 \text{ stations} = 3.138 \text{ patients per station per week} / 4 = 0.7846$ ). The projected utilization of 3.14 patients per station per week for OY1 satisfies the 2.8 in-center patients per station threshold for the first year following completion of the project, as required by 10A NCAC 14C .2203(b).

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

- The applicant bases the beginning in-center patient census on the ending census of the previous year, CY2020, the most recent historical patient census, as submitted to the DHSR HealthCare Planning Section.
- The new stations are expected to be certified as of December 31, 2022, which makes CY2023 the first full FY and CY2024 the second full FY.
- The applicant projects the growth of the Cumberland County patient census using the Five-Year AACR of 5.2%, as reported in the 2021 SMFP and does not grow the census of the patients from outside Cumberland County.
- The applicant reduces the patient census by the 13 patients projected to transfer to FKC Hope Mills as of December 31, 2022.

- The projected utilization rate by the end of OY1 exceeds the minimum standard of 2.8 patients per station per week.

**Access to Medically Underserved Groups**

In Section C.6, page 31, the applicant discusses access to the facility’s services, stating:

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

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

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

The applicant provides the estimated percentage for each medically underserved group to be served in the second year of operation on page 31, as summarized in the following table.

<b>Medically Underserved Groups</b>	<b>Percentage of Total Patients</b>
Low income persons	92.5%
Racial and ethnic minorities	88.2%
Women	49.1%
Persons with Disabilities	37.3%
Persons 65 and older	54.0%
Medicare beneficiaries	79.5%
Medicaid recipients	45.3%

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

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

**Conclusion**

The Agency reviewed the:

- Application

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

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

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

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, 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 no more than six dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 56 stations at FMC South Ramsey upon completion of this project, Project ID# M-12038-21 (add 9), and Project ID# M-12129-21 (relocate 6).

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:

- Maintain the status quo – the applicant states that failure to apply for additional stations would result in higher utilization rates and potentially interrupt patient admissions; thus, this alternative is not the most effective.
- Add fewer than six stations – the applicant states that this alternative would also result in higher utilization rates as the facility patient census increases; thus, this is not the most effective alternative.
- Add as many as 11 stations (2021 SMFP FMC South Ramsey needed stations (20) less previously approved 2021 stations (9) = 11) – the applicant states that this alternative

would not be cost effective because the facility can only accommodate a total of six additional stations; thus, this is not the most effective alternative.

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

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

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

### **Conclusion**

The Agency reviewed the:

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

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

- 1. Bio-Medical Applications of North Carolina, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. Pursuant to Condition 2 of the facility need determination in the 2021 SMFP, the certificate holder shall develop no more than six additional in-center dialysis stations for a total of no more 56 stations at FMC Dialysis Services of South Ramsey upon completion of this project, Project ID #M-12038-21 (add 9) and Project ID # M-12129-21 (relocate 6).**
- 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 November 1, 2022. The second progress report shall be due on March 1, 2023 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 six dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 56 stations at FMC South Ramsey upon completion of this project, Project ID# M-12038-21 (add 9), and Project ID# M-12129-21 (relocate 6).

**Capital and Working Capital Costs**

In Section C.1, page 42, and Section Q Form F.1a Capital Cost, page 87, the applicant states that the project will require no total capital cost.

In Sections F.3, page 44, the applicant states there will be no start-up or initial operating expenses associated with the proposed project since this is an existing facility that is already operational.

**Financial Feasibility**

The applicant provides pro forma financial statements for the first two full operating years following completion of the project. In Form F.2, page 89, 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 South Ramsey Projected Revenue and Operating Expenses**

	<i>Interim Full FY</i>	<i>Interim Full FY</i>	<i>1<sup>st</sup> Full FY</i>	<i>2<sup>nd</sup> Full FY</i>
	<b>CY2021</b>	<b>CY2022</b>	<b>CY2023</b>	<b>CY2024</b>
<i>Total In-Center Treatments</i>	24,744	26,015	26,340	26,682
Total Gross Revenues (Charges)	\$ 155,661,535	\$ 163,659,103	\$ 165,705,903	\$ 167,859,136
Total Net Revenue	\$ 6,734,268	\$ 7,080,260	\$ 7,168,810	\$ 7,261,963
Avg Net Revenue per Treatment	\$ 272	\$ 272	\$ 272	\$ 272
Total Operating Expenses (Costs)	\$ 5,767,675	\$ 5,941,050	\$ 6,021,785	\$ 6,105,112
Avg Op. Expense per Treatment	\$ 233	\$ 228	\$ 229	\$ 229
Net Income	\$ 966,593	\$ 1,139,210	\$ 1,147,025	\$ 1,156,851

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

- Gross revenue per treatment is \$6,291
- Contractual adjustments are calculated by payor class for each year
- Salaries are projected to increase at 2% annually
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference

**Conclusion**

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion for because the applicant adequately demonstrates the availability of sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges

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

C

The applicant proposes to add no more than six dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 56 stations at FMC South Ramsey upon completion of this project, Project ID# M-12038-21 (add 9), and Project ID# M-12129-21 (relocate 6).

Page 113 of the 2021 SMFP defines the service area for the county need methodology for dialysis stations as *“the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay, and Graham counties and Avery, Mitchell, and Yancey counties.”* The facility in this application is in Cumberland County. Thus, the service area for this application is Cumberland County. Facilities may serve residents of counties not included in their service area.

Section G.1 of the application requires the use of Table 9A in the Proposed SMFP for the following year for applications with submission deadlines July to December. This application had a submission deadline of November 15, 2021; thus, Table 9A in the Proposed 2022 SMFP applies for this Section. According to Table 9A of the Proposed 2022 SMFP (signed by the Governor subsequent to the submission of the application), there are six existing or approved dialysis facilities in Cumberland County. Information on the Cumberland County dialysis facilities, from Table 9A of the signed 2022 SMFP, is provided below:

**Cumberland County Dialysis Facilities  
 Certified Stations and Utilization as of December 31, 2020**

Dialysis Facility	Owner	# of Certified Stations *	# IC Patients **	Utilization ***	Patients / Station	# Additional Approved Stations ^
Fayetteville Kidney Center	Fresenius	56	167	74.55%	2.9821	0
FMC Dialysis Services North Ramsey	Fresenius	40	152	95.00%	3.8000	10
FMC Dialysis Services South Ramsey	Fresenius	47	163	86.70%	3.4681	9
FMC Services of West Fayetteville	Fresenius	40	173	108.13%	4.3250	0
Fresenius Kidney Care Hope Mills	Fresenius	0	0	0.00%	0.0000	0
Fresenius Kidney Care Rockfish	Fresenius	25	68	68.00%	2.7200	0
Total Cumberland County		208	723	86.90%	3.4759	

\* From Column K in Table 9A.

\*\* From Column L in Table 9A.

\*\*\* From Column M in Table 9A.

^ Sum of Column G Cons Issued/Not Certified and Column H Decision Rendered (Conditional Approval) in Table 9A.

Agency data shows that all six Cumberland County facilities are owned and operated by Fresenius. The final column in the above table shows the number of approved, but not yet certified stations at each facility in Cumberland County, as of December 31, 2020.

In Section G, pages 49-50, 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 that this application is based upon facility performance and demonstrated need at FMC South Ramsey and is not specific to Cumberland County as a whole. The applicant states that of its operational facilities in Cumberland County, only Fresenius Kidney Care Rockfish had utilization lower than 70% for CY 2020 and its utilization was artificially decreased because Fresenius has set aside half of that facility for COVID patients. The applicant further states that while some capacity does exist at Fayetteville Kidney Center and FMC Dialysis Services North Ramsey, those facilities are not strategically located to serve the same patients as FMC South Ramsey.

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

- The applicant adequately demonstrates that FMC South Ramsey needs additional stations to serve its existing and projected patient population.
- The applicant adequately demonstrates that the proposed additional stations are needed in addition to the existing and approved stations in Cumberland County.

### **Conclusion**

The Agency reviewed the:

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

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

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

### C

The applicant proposes to add no more than six dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 56 stations at FMC South Ramsey upon completion of this project, Project ID# M-12038-21 (add 9), and Project ID# M-12129-21 (relocate 6).

In Section Q Form H, page 97, the applicant provides current and projected full-time equivalent (FTE) positions for the FMC South Ramsey facility, as summarized in the following table:

POSITION	Current FTE Positions	FTE POSITIONS CY2023	FTE POSITIONS CY2024
Administrator	1.00	1.00	1.00
RN	8.00	8.00	8.00
Patient Care Technician (PCT)	21.00	21.00	21.00
Dietician	1.00	1.00	1.00
Social Worker	1.00	1.00	1.00
Maintenance	1.00	1.00	1.00
Administration/Business Office	1.00	1.00	1.00
FMC Director Operations	0.15	0.15	0.15
FMC Chief Technician	0.15	0.15	0.15
FMC In-Service	0.25	0.25	0.25
<b>Total</b>	<b>34.55</b>	<b>34.55</b>	<b>34.55</b>

Source: Section Q Form H, page 97

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.4. In Section H, pages 52-53, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

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

- The facility is an existing facility and the applicant bases its staffing on its historical experience providing dialysis services at the facility
- The applicant has existing policies in regard to recruitment, training and continuing education

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to add no more than six dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 56 stations at FMC South Ramsey upon completion of this project, Project ID# M-12038-21 (add 9), and Project ID# M-12129-21 (relocate 6).

**Ancillary and Support Services**

In the table in Section I, page 54, the applicant identifies each ancillary and support service listed in the application as necessary for the proposed services. On pages 54-59, the applicant explains how each ancillary and support service is made available.

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

**Coordination**

In Section I, page 59, the applicant describes its existing relationships with other local health care and social service providers.

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

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

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. 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 January 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 proposes to add no more than six dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 56 stations at FMC South Ramsey upon completion of this project, Project ID# M-12038-21 (add 9), and Project ID# M-12129-21 (relocate 6). The stations will backfill spaces where stations have been approved for relocation and the applicant does not propose any construction or renovation.

- (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 67, the applicant provides the historical payor mix for in-center dialysis during CY2020 for FMC South Ramsey, as summarized in the table below.

Primary Payor Source at Admission	In-center Dialysis	
	# of Patients	% of Total
Self-Pay	2.3	1.4%
Insurance *	3.5	4.0%
Medicare *	133.0	81.6%
Medicaid *	9.7	5.9%
Other (Misc. including VA)	11.5	7.1%
<b>Total</b>	<b>163.0</b>	<b>100.00%</b>

\*Including any managed care plans

In Section L, page 68, the applicant provides the following comparison.

FMC SOUTH RAMSEY	Percentage of Total Patients Served by the Facility	Percentage of the Population of the Service Area
Female	49.1%	50.4%
Male	50.9%	49.6%
Unknown		
64 and Younger	46.0%	87.8%
65 and Older	54.0%	12.2%
American Indian	2.48%	1.9%
Asian	0.0%	2.7%
Black or African-American	80.1%	39.1%
Native Hawaiian or Pacific Islander	0.0%	0.4%
White or Caucasian	11.8%	42.4%
Other Race	5.6%	13.5%
Declined / Unavailable	0.0%	

The Agency reviewed the:

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

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

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 69, the applicant states that FMC South Ramsey is not obligated under any applicable federal regulations to provide uncompensated care, community service, or access by minorities and persons with disabilities.

In Section L, page 69, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against the facility identified in Section A, Question 4.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L.3, page 70, the applicant projects the payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as summarized in the table below.

**FMC South Ramsey Projected Payor Mix  
Second Full FY of Operation following Project Completion  
01/01/2023 to 12/31/2023 [CY2024]**

County	IC Patients	
	Patients	% of Total
Self-Pay	2.6	1.4%
Insurance *	7.4	4.0%
Medicare *	150.8	81.6%
Medicaid *	11.0	5.9%
Other (Misc., including VA)	13.1	7.1%
<b>Total</b>	<b>184.8</b>	<b>100.0%</b>

\*Including any managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 1.4% of FMC South Ramsey's dialysis services will be provided to self-pay patients, 81.6% to Medicare recipients and 5.9% to Medicaid recipients.

On page 70, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

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

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

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

The Agency reviewed the:

- Application

- Exhibits to the application

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

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

### C

The applicant proposes to add no more than six dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 56 stations at FMC South Ramsey upon completion of this project, Project ID# M-12038-21 (add 9), and Project ID# M-12129-21 (relocate 6).

In Section M, page 73, 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. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- The applicant currently provides applicable health professional training programs in the area with access to the facility
- The applicant provides documentation of its willingness to provide applicable health professional training programs in the area with access to the facility

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to add no more than six dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 56 stations at FMC South Ramsey upon completion of this project, Project ID# M-12038-21 (add 9), and Project ID# M-12129-21 (relocate 6).

Page 113 of the 2021 SMFP defines the service area for the county need methodology for dialysis stations as *“the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay, and Graham counties and Avery, Mitchell, and Yancey counties.”* The facility in this application is in Cumberland County. Thus, the service area for this application is Cumberland County. Facilities may serve residents of counties not included in their service area.

Section G.1 of the application requires the use of Table 9A in the Proposed SMFP for the following year for applications with submission deadlines July to December. This application had a submission deadline of November 15, 2021; thus, Table 9A in the Proposed 2022 SMFP applies for this Section. According to Table 9A of the Proposed 2022 SMFP (signed by the Governor subsequent to the submission of the application), there are six existing or approved dialysis facilities in Cumberland County. Information on the Cumberland County dialysis facilities, from Table 9A of the signed 2022 SMFP, is provided below:

**Cumberland County Dialysis Facilities  
 Certified Stations and Utilization as of December 31, 2020**

Dialysis Facility	Owner	# of Certified Stations *	# IC Patients **	Utilization ***	Patients / Station	# Additional Approved Stations ^
Fayetteville Kidney Center	Fresenius	56	167	74.55%	2.9821	0
FMC Dialysis Services North Ramsey	Fresenius	40	152	95.00%	3.8000	10
FMC Dialysis Services South Ramsey	Fresenius	47	163	86.70%	3.4681	9
FMC Services of West Fayetteville	Fresenius	40	173	108.13%	4.3250	0
Fresenius Kidney Care Hope Mills	Fresenius	0	0	0.00%	0.0000	0
Fresenius Kidney Care Rockfish	Fresenius	25	68	68.00%	2.7200	0
Total Cumberland County		208	723	86.90%	3.4759	

\* From Column K in Table 9A.

\*\* From Column L in Table 9A.

\*\*\* From Column M in Table 9A.

^ Sum of Column G Cons Issued/Not Certified and Column H Decision Rendered (Conditional Approval) in Table 9A.

Agency data shows that all six Cumberland County facilities are owned and operated by Fresenius. The final column in the above table shows the number of approved, but not yet certified stations at each facility in Cumberland County, as of December 31, 2020.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 74, 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 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, pages 74-75, the applicant states:

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

...

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

...

*Approval of this application will allow the facility to continue serving dialysis patients residing in the area. Consequently, these patients will have a shorter commute to and from dialysis treatment.”*

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

Regarding the impact of the proposal on quality, in Section N, page 75, the applicant states:

*“Quality of care is always in the forefront at Fresenius Medical Care related facilities. Quality of care is not negotiable. Fresenius Medical Care, parent organization for this facility, expects every facility to provide high quality care to every patient at every treatment. Our organizational mission statement captures this sentiment very well:*

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

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 75, the applicant states:

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

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

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

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

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

### **Conclusion**

The Agency reviewed the:

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

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

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

### C

In Section Q Form O, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies over 120 dialysis facilities owned, operated, or managed by a Fresenius Medical Care related entity and located in North Carolina.

In Section O, page 80, the applicant states that, during the 18 months immediately preceding the submittal of the application, no Fresenius related facility has been found to have had an incident related to quality of care that resulted in a finding of “*Immediate Jeopardy*”. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all Fresenius facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

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

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

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

-NA- FMC South Ramsey is an existing facility. Therefore, this Rule is not applicable to this review.

- (b) *An applicant proposing to increase the number of dialysis stations in:*
- (1) *an existing dialysis facility; or*
  - (2) *a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need;*

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

- C- In Section C, page 33, and on Section Q Form C Utilization, the applicant projects that FMC South Ramsey will serve 175.8 in-center patients on 56 stations, a utilization rate of 3.14 ( $175.8 / 56 = 3.14$ ) patients per station per week, as of the end of the first operating year following project completion, exceeding the 2.8 patients per station per week requirement. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
  
- (c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
  
- C- In Section C, pages 26-27, and in Section Q Form C Utilization subsection, pages 84-85, 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.