

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: Lisa Pittman

Project ID #: L-12165-21

Facility: Rocky Mount Kidney Center

FID #: 944658

County: Nash

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

Project: Add no more than 10 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 50 stations upon project completion

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 10 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 50 stations at Rocky Mount Kidney Center upon project completion.

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 135, the county need methodology shows there is not a county need determination for additional dialysis stations in Nash 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 128, the utilization rate reported for the facility is 86.25% or 3.45 patients per station per week, based on 138 in-center dialysis patients and 40 certified dialysis stations ($138 \text{ patients} / 40 \text{ stations} = 3.45$; $3.45 / 4 = 0.8625$).

As shown in Table 9D, page 139, based on the facility need methodology for dialysis stations, the potential number of stations needed is up to 11 additional stations; thus, the applicant is eligible to apply to add up to 11 stations during the 2021 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than 10 new stations to the facility, which is consistent with the 2021 SMFP calculated facility need determination for up to 11 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, pages 21-22; Section N, page 74; Section O, pages 76-79; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project will promote equitable access in Section B, page 22; Section C, page 32; Section L, pages 66-69; Section N, page 74; 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 73-74; 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 10 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 50 stations at Rocky Mount Kidney Center upon project completion.

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.” Rocky Mount Kidney Center is located in Nash County. Thus, the service area for this application is Nash 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 Rocky Mount Kidney Center, 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)**

County	Patients	% of Total
Nash	88	59.9%
Edgecombe	39	26.5%
Halifax	19	12.9%
Warren	1	0.7%
Total	147	100.0%

Source: Section C.2, page 25

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

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

County	Patients	% of Total
Nash	93.4	58.2%
Edgecombe	47	29.3%
Halifax	19	11.8%
Warren	1	0.6%
Total	160.4	100.0%

Source: Section C.3, 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 10 stations to Rocky Mount Kidney Center for a total of 50 stations upon project completion. The facility will continue to offer in-center dialysis and is not currently offering or proposing to offer home dialysis training and support services as part of this application.”

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, 1.2% and 3.8%, for predicting growth of the Nash and Edgecombe County patients, respectively.
- The applicant assumes the 20 patients from the counties of Halifax and Warren will continue to dialyze at the facility and adds the 20 patients for future projections, with no growth.
- The applicant assumes patients from other counties and states to be transient and does not include these patients going forward.
- The proposed new stations are projected to be certified as of December 31, 2023.
- Operating Year (OY) 1 is CY2024. OY2 is CY2025.

Analysis of Need

In Section C, page 29, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. 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 157.6 in-center dialysis patients dialyzing with the facility as of the end of the first Operating Year of the project. This equates to a utilization rate of 78.8%, or 3.15 patients per station and exceeds the minimum required by the performance standard.”

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

- Page 139 of the 2021 SMFP shows a facility need determination for up to 11 stations at Rocky Mount Kidney Center.
- The applicant applies the Nash and Edgecombe County AACRs as provided in the 2021 SMFP to project growth in Nash and Edgecombe County patient utilization.
- The applicant assumes patients from Halifax and Warren 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 82, 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

Form C Utilization	Last Full FY CY2020	Interim FY CY2021	Interim FY CY2022	Interim FY CY2023	1st Full FY CY2024	2nd Full FY CY2025
In-Center Patients						
# of Patients at the Beginning of the Year	138	147	150	152	155	158
# of Patients at the End of the Year	147	150	152	155	158	160
Average # of IC Patients during the Year	143	148	151	153	156	159
# of Treatments / Patient / Year	148	148	148	148	148	148
Total # of Treatments	21,738	21,944	22,325	22,716	23,117	23,530

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 calculations 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 on page 82.

In Section C, pages 26-27 and Section Q, pages 84-86, the applicant provides the assumptions and methodology used to project in-center utilization, which are summarized below.

- The first full FY is CY2024, the period from January 1-December 31, 2024
- The second full FY is CY2025
- Projections begin with the facility census as of December 31, 2020
- The applicant grows the Nash and Edgecombe County patient census by 1.2% and 3.8%, respectively, the 5-year AACRs as found in the 2021 SMFP, pages 135 and 134, respectively
- The facility also serves 20 in-center patients residing in Halifax and Warren counties, which the applicant states are assumed to continue to dialyze at the facility, but the utilization is not projected to grow

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

Projected Rocky Mount Kidney Center In-Center Patients	
Begin with the Nash and Edgecombe County patient populations, as of December 31, 2020.	88 39
Project the Nash and Edgecombe County patient population forward one year to December 31, 2021, using the Five-Year AACR (1.2% and 3.8%, respectively).	$88.0 \times 1.012 = 89.1$ $39.0 \times 1.038 = 40.5$
Project the Nash and Edgecombe County patient population forward one year to December 31, 2022, using the Five-Year AACR (1.2% and 3.8%, respectively).	$89.1 \times 1.012 = 90.1$ $40.5 \times 1.038 = 42.0$
Project the Nash and Edgecombe County patient population forward one year to December 31, 2023, using the Five-Year AACR (1.2% and 3.8%, respectively).	$90.1 \times 1.012 = 91.2$ $42.0 \times 1.038 = 43.6$
Add the 20 patients from other counties who will continue to dialyze at the facility. This is the projected starting census for this project on December 31, 2023.	$91.2 + 43.6 + 20 = 154.8$
Project the Nash and Edgecombe County patient population forward one year to December 31, 2024, using the Five-Year AACR (1.2% and 3.8%, respectively).	$91.2 \times 1.012 = 92.3$ $43.6 \times 1.038 = 45.3$
Add the 20 patients from other counties. This is the projected ending census for Operating Year 1, CY2024.	$92.3 + 45.3 + 20 = 157.6$
Project the Nash and Edgecombe County patient population forward one year to December 31, 2025, using the Five-Year AACR (1.2% and 3.8%, respectively).	$92.3 \times 1.012 = 93.4$ $45.3 \times 1.038 = 47.0$
Add the 20 patients from other counties. This is the projected ending census for Operating Year 2, CY20245	$93.4 + 47.0 + 20 = 160.4$

Totals may not sum due to rounding

As the table above shows, using conventional rounding, the applicant’s methodology achieves a projection of 157.6 in-center patients by the end of the first full FY, OY1 (December 31, 2024), for a utilization rate of 3.15 patients per station per week or 78.8% ($157.6 \text{ patients} / 50 \text{ stations} = 3.152 \text{ patients per station per week} / 4 = 0.788$). By the end of OY2 (December 31, 2025), following the applicant’s methodology and assumptions, the facility will have 160.4 in-center patients dialyzing at the center for a utilization rate of 80.2% ($160.4 / 50 = 3.21 / 4 = 0.802$). The projected utilization of 3.15 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, 2023, which makes CY2024 the first full FY and CY2025 the second full FY.
- The applicant projects the growth of the Nash and Edgecombe County patient census using the Five-Year AACRs of 1.2% and 3.8%, respectively, as reported in the 2021

SMFP and does not grow the census of the patients from outside Nash and Edgecombe counties.

- 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 32, 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 32, as summarized in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low income persons	47.97%
Racial and ethnic minorities	80.41%
Women	37.84%
Persons with Disabilities	20.27%
Persons 65 and older	54.05%
Medicare beneficiaries	56.08%
Medicaid recipients	42.57%

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 10 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 50 stations at Rocky Mount Kidney Center upon project completion.

In Section E, page 41, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the status quo – the applicant states that 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 10 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 – the applicant states that this alternative would not be cost effective because the facility can only accommodate 10 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 10 additional in-center dialysis stations for a total of no more 50 stations at Rocky Mounty Kidney Center upon project completion.**
- 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 10 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 50 stations at Rocky Mount Kidney Center upon project completion.

Capital and Working Capital Costs

In Section Q Form F.1a Capital Cost, page 88, the applicant projects the total capital cost of the project, as summarized below.

Construction/Renovation Costs/ A&E	\$1,087,115
Equipment /Furniture /Fixtures Costs	\$133,449
Contingency	\$163,067
Total	\$1,383,631

In Section Q, page 89, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- Construction costs estimated based on national data base used by the Fresenius Real Estate and Construction Services team
- Cost of equipment, furniture and fixtures estimated based on experience purchasing such items at existing facilities

In Sections F.3, page 45, the applicant states there will be no start-up or initial operating expenses associated with the proposed project since this is an existing facility that is already operational.

Availability of Funds

In Section F.2, page 43, the applicant states that the capital cost will be funded as shown in the table below.

Type	Bio-Medical Applications of North Carolina, Inc.
Loans	
Cash and Cash Equivalents, Accumulated reserves or OE *	\$1,383,631
Bonds	
Other (Specify)	
Total Financing	\$1,383,631

* OE = Owner's Equity

Exhibit F-2 contains a letter dated November 15, 2021 from the Senior Vice President and Treasurer, authorizing and committing accumulated reserves of Fresenius Medical Care Holdings (FMCH), the parent company for BMA, for the \$1,383,631 capital costs of the project. The letter also documents that the 2020 Consolidated Balance Sheet for FMCH reflects more than \$446 million in cash, and total assets exceeding \$25 billion.

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 91, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as summarized in the table below.

Rocky Mount Kidney Center Projected Revenue and Operating Expenses

	<i>Interim Full FY</i>	<i>Interim Full FY</i>	<i>Interim Full FY</i>	<i>1st Full FY</i>	<i>2nd Full FY</i>
	<i>CY2021</i>	<i>CY2022</i>	<i>CY2023</i>	<i>CY2024</i>	<i>CY2025</i>
<i>Total In-Center Treatments</i>	21,944	22,325	22,716	23,117	23,530
Total Gross Revenues (Charges)	\$ 138,048,521	\$ 140,443,688	\$ 142,904,155	\$ 145,432,093	\$ 148,029,756
Total Net Revenue	\$ 5,985,455	\$ 6,089,303	\$ 6,195,984	\$ 6,305,589	\$ 6,418,217
Avg Net Revenue per Treatment	\$ 273	\$ 273	\$ 273	\$ 273	\$ 273
Total Operating Expenses (Costs)	\$ 4,921,266	\$ 4,998,928	\$ 5,266,745	\$ 5,519,916	\$ 5,606,960
Avg Op. Expense per Treatment	\$ 224	\$ 224	\$ 232	\$ 239	\$ 238
Net Income	\$ 1,064,189	\$ 1,090,375	\$ 929,239	\$ 785,673	\$ 811,257

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 10 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 50 stations at Rocky Mount Kidney Center upon project completion.

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 Nash County. Thus, the service area for this application is Nash County. Facilities may serve residents of counties not included in their service area.

According to Table 9A of the Proposed 2022 SMFP (signed by the Governor subsequent to the submission of the application), there are four existing or approved dialysis facilities in Nash County. 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 2022 SMFP applies for this Section. Information on the Nash County dialysis facilities, from Table 9A of the 2022 SMFP, is provided below:

**Nash 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 ^
FMC of Spring Hope	Fresenius	16	39	60.94%	2.4375	0
Fresenius Medical Care South Rocky Mount	Fresenius	19	68	89.47%	3.5789	0
Nash County Dialysis	Fresenius	12	29	60.42%	2.4167	0
Rocky Mount Kidney Center	Fresenius	40	147	91.88%	3.6750	0
Total Nash County		87	283	81.32%	3.2529	

* 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 four Nash 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 Nash 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 Nash County. The applicant states that this application is based upon facility performance and demonstrated need at Rocky Mount Kidney Center and is not specific to Nash County as a whole.

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

- The applicant adequately demonstrates that Rocky Mount Kidney Center 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 Nash 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 10 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 50 stations at Rocky Mount Kidney Center upon project completion.

In Section Q Form H, pages 99-100, the applicant provides current and projected full-time equivalent (FTE) positions for the Rocky Mount Kidney Center facility, as summarized in the following table:

POSITION	Current FTE Positions	FTE POSITIONS CY2024	FTE POSITIONS CY2025
Administrator	1.00	1.00	1.00
RN	7.00	8.00	8.00
Patient Care Technician (PCT)	13.00	15.00	15.00
Dietician	1.50	1.50	1.50
Social Worker	1.50	1.50	1.50
Maintenance	1.00	1.00	1.00
Administration/Business Office	1.00	1.00	1.00
FMC Director Operations	0.20	0.20	0.20
FMC Chief Technician	0.20	0.20	0.20
FMC In-Service	0.25	0.25	0.25
Total	26.65	29.65	29.65

Source: Section Q Form H, pages 99-100

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

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

- The facility is an existing facility and the applicant bases its staffing on its historical experience providing dialysis services at the facility
- The applicant has existing policies 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 10 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 50 stations at Rocky Mount Kidney Center upon project completion.

Ancillary and Support Services

In the table in Section I, page 53, the applicant identifies each ancillary and support service listed in the application as necessary for the proposed services. On pages 53-58, 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 Rocky Mount Kidney Center.

Coordination

In Section I, page 58, 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.

C

The applicant proposes to add no more than 10 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 50 stations at Rocky Mount Kidney Center upon project completion.

In Section K, page 61, the applicant states that the project will involve renovation of 1,000 square feet. The proposed floor plan is provided in Exhibit K-2.

On pages 61-62, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following:

- The applicant will renovate existing space
- Fresenius Medical Care has extensive experience designing dialysis facilities
- Line drawings are provided in Exhibit K-2

On page 62, the applicant adequately explains 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 based on the following:

- The proposed project to add stations is necessary to ensure continued convenient access to care for the patients in the area
- The cost of adding stations is not passed on the patient - the costs are borne by BMA.
- The applicant states that the proposed project will not increase costs or charges to the public for the proposed services

On pages 62-63, the applicant provides the applicable energy saving features that are incorporated Fresenius related dialysis facilities.

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.

- (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 66, the applicant provides the historical payor mix for in-center dialysis during CY2020 for Rocky Mount Kidney Center, as summarized in the table below.

Primary Payor Source at Admission	In-center Dialysis	
	# of Patients	% of Total
Self-Pay	1.1	0.77%
Insurance *	7.0	4.75%
Medicare *	119.2	81.09%
Medicaid *	11.9	8.12%
Other (VA and Misc.)	7.7	5.27%
Total	147.0	100.00%

*Including any managed care plans

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

ROCKY MOUNT KIDNEY CENTER	Percentage of Total Patients Served by the Facility	Percentage of the Population of the Service Area
Female	37.8%	52.1%
Male	62.2%	47.9%
Unknown		
64 and Younger	46.0%	81.0%
65 and Older	54.1%	19.0%
American Indian	0.7%	1.0%
Asian	1.4%	1.0%
Black or African-American	76.4%	41.3%
Native Hawaiian or Pacific Islander	0.7%	0.1%
White or Caucasian	19.6%	54.7%
Other Race	1.4%	9.3%
Declined / Unavailable	0.0%	0.0%

The Agency reviewed the:

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

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

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities

and ... persons [with disabilities] to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 68, the applicant states that Rocky Mount Kidney Center 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 68, 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 69, 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.

**Rocky Mount Kidney Center Projected Payor Mix
Second Full FY of Operation following Project Completion
CY2025**

County	IC Patients	
	Patients	% of Total
Self-Pay	1.2	0.77%
Insurance *	7.6	4.75%
Medicare *	130.1	81.09%
Medicaid *	13.0	8.12%
Other (Misc., including VA)	8.5	5.27%
Total	160.4	100.0%

*Including any managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 0.77% of Rocky Mount Kidney Center's dialysis services will be provided to self-pay patients, 81.09% to Medicare recipients and 8.12% to Medicaid recipients.

On pages 69-70, 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 71, 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 10 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 50 stations at Rocky Mount Kidney Center upon project completion.

In Section M, page 72, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M. 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 10 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 50 stations at Rocky Mount Kidney Center upon project completion.

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 Nash County. Thus, the service area for this application is Nash County. Facilities may serve residents of counties not included in their service area.

According to Table 9A of the Proposed 2022 SMFP, there are four existing or approved dialysis facilities in Nash County. 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 2022 SMFP applies for this Section. Information on the Nash County dialysis facilities, from Table 9A of the 2022 SMFP, is provided below:

**Nash 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 ^
FMC of Spring Hope	Fresenius	16	39	60.94%	2.4375	0
Fresenius Medical Care South Rocky Mount	Fresenius	19	68	89.47%	3.5789	0
Nash County Dialysis	Fresenius	12	29	60.42%	2.4167	0
Rocky Mount Kidney Center	Fresenius	40	147	91.88%	3.6750	0
Total Nash County		87	283	81.32%	3.2529	

* 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 four Nash 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 Nash County, as of December 31, 2020.

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

“The applicant does not expect this proposal to have any effect on the competitive climate in Union [sic] County. The applicant does not project to serve dialysis patients currently being served by another provider. The projected patient population for the facility begins with the current patient population, projected patient transfers, and growth of that population consistent with the Nash and Edgecombe 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 73-74, 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 74, 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 74, the applicant states:

“It is corporate policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, 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 79, the applicant states that, during the 18 months immediately preceding the submittal of the application, no Fresenius related facility has been found to have had an incident related to quality of care that resulted in a finding of "*Immediate Jeopardy*". After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all Fresenius facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective 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- Rocky Mount Kidney Center 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 29, and on Section Q Form C Utilization, the applicant projects that Rocky Mount Kidney Center will serve 157.6 in-center patients on 50 stations, a utilization rate of 3.15 ($157.6 / 50 = 3.15$) 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 84-86, 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.