

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: April 27, 2022

Findings Date: April 27, 2022

Project Analyst: Gregory F. Yakaboski

Co-Signer: Micheala L. Mitchell

Project ID #: L-12160-21

Facility: BMA East Rocky Mount

FID #: 970528

County: Edgecombe

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 30 stations upon completion of this project and Project ID #L-12135-21 (relocate 6)

### REVIEW CRITERIA

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

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

### C

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 30 stations at BMA East Rocky Mount upon completion of this project and Project ID #L-12135-21 (relocate 6 from BMA East Rocky Mount to Fresenius Kidney Care (FKC) Boice-Willis)

BMA is a wholly owned subsidiary of Fresenius Medical Care Holdings, Inc. (FMC or Fresenius).

BMA East Rocky Mount provides in-center (IC) dialysis but does not currently offer either a peritoneal dialysis (PD) program or a home hemodialysis (HH) program.

## **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 134, the county need methodology shows there is not a county need determination for additional dialysis stations in Edgecombe 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 122, the utilization rate reported for the facility is 95.00% or 3.8 patients per station per week, based on 114 in-center dialysis patients and 30 certified dialysis stations [114 patients / 30 stations = 3.8;  $3.8 / 4 = 0.95$  or 95.0%).

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 thirteen additional stations; the applicant has not applied for any additional dialysis stations, prior to this application, during the 2021 SMFP review cycle, thus, the applicant is eligible to apply to add up to 13 dialysis stations pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than six new stations to the facility, which is consistent with the 2021 SMFP calculated facility need determination for up to 13 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 73; Section O, pages 75-78; and referenced exhibits.

The information provided by the applicant is reasonable and supports the determination that the applicant's proposal will promote safety and quality in the delivery of dialysis services.

### Promote Equitable Access

The applicant describes how it believes the proposed project will promote equitable access in Section B, page 22; Section C, page 33; Section L, pages 65-69; Section N, page 73; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant's proposal will promote equitable access to dialysis services.

### 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 72-73; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant's proposal will maximize healthcare value for dialysis services.

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 July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities,

women, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

**C**

The applicant proposes to add no more than six dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 30 stations at BMA East Rocky Mount upon completion of this project and Project ID #L-12135-21 (relocate 6 to FKC Boice-Willis).

**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.*” BMA East Rocky Mount is in Edgecombe County. Thus, the service area for this application is Edgecombe County. Facilities may serve residents of counties not included in their service area.

The following table illustrates historical and projected patient origin.

County	Historical (CY2020)		Second Full FY of Operation following Project Completion (CY2024)	
	Patients	% of Total	Patients	% of Total
Edgecombe	76	67.90%	59.1	61.20%
Nash	32	28.60%	33.6	34.70%
Halifax	3	2.70%	3	3.10%
Wilson	1	0.90%	1	1.09%
Total	112	100.0%	96.7	100.00%

Source: Tables on pages 25 & 26 of the application.  
 Note: Totals might not sum due to rounding error.

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

- The applicant begins with the historical December 31, 2020 patient census.
- The applicant uses the 3.8% Edgecombe County 5-year Average Annual Change Rate (AACR) as published in the 2021 SMFP to project patient growth for the Edgecombe County patient population.
- The applicant uses the 1.2% Nash County AACR as published in the 2021 SMFP to project patient growth for the Nash County patient population.
- The applicant assumes the four patients from the contiguous counties of Halifax and Wilson will continue to dialyze at the facility and adds the four patients for future projections, with no growth.
- Project ID #L-12135-21 proposed to relocate six stations and transfer 27 Edgecombe County patients from BMA East Rocky Mount to FKC Boice-Willis upon completion

of the project at December 31, 2022. The applicant subtracts 27 Edgecombe County patients as of December 31, 2022.

- The proposed new stations are projected to be certified as of December 31, 2022.
- Operating Year (OY) 1 is CY2023. OY2 is CY2024.

**Analysis of Need**

In Section C, pages 29-31, 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 94.1 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 78.45%, 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 thirteen stations at BMA Rocky Mount.
- The applicant applies the Edgecombe and Nash Counties AACR as provided in the 2021 SMFP to project growth in Edgecombe and Nash Counties patient utilization and does not project a growth for patients from outside either Edgecombe or Nash County.
- The applicant reduces the utilization by the number of patients proposed to transfer to FKC Boice-Willis in Project ID #L-12135-21.
- The applicant demonstrates that the facility will need the additional stations to accommodate the existing and projected patient population

**Projected Utilization**

In Section Q Form C, page 81, the applicant provides the historical, interim and 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	114	112	115	92	94
# of Patients at the End of the Year	112	115	119	94	97
Average # of IC Patients during the Year	113	114	117	93	95
# of Treatments / Patient / Year	148	148	148	148	148
Total # of Treatments	16,748	16,818	17,311	13,749	14,122

Source: See Table on page 81 of the application.

In Section C, page 26 and Section Q, page 82, the applicant provides the assumptions and methodology used to project utilization, as summarized below:

- The applicant begins with the December 31, 2020 patients who are currently served at BMA East Rocky Mount.
- The applicant begins its utilization projections by using the BMA East Rocky Mount patient census as of December 31, 2020: 76 Edgecombe County patients, 32 Nash County patients, 3 Halifax County patients and 1 Wilson County patient.
- The applicant uses the 3.8% Edgecombe County AACR as published in the 2021 SMFP to project patient growth for the Edgecombe County patient population.
- The applicant uses the 1.2% Nash County AACR as published in the 2021 SMFP to project patient growth for the Nash County patient population.
- Halifax and Wilson counties are contiguous to Edgecombe County. The applicant expects these patients to continue dialysis at BMA East Rocky Mount as a matter of patient choice however, the applicant does not project growth in that patient population. The applicant does add those patients to its patient projections at the appropriate points in time.
- The applicant states this application follows Project ID #L-12135-21 in which the applicant proposed to relocate six stations and transfer 27 Edgecombe County patients from BMA East Rocky Mount to FKC Boice-Willis upon completion of the project at December 31, 2022. The applicant subtracts 27 Edgecombe County patients as of December 31, 2022.
- The applicant projects the stations proposed in this application to be certified as of December 31, 2022. The project proposes to install the proposed dialysis stations in existing space.
- The applicant states Operating Year (OY) one is calendar year (CY) 2023, and OY 2 is CY 2024.

The applicant provides a table in Section C, page 27, and in Section Q, page 83 to illustrate the application of its assumptions and methodology, as shown below:

	Edgecombe	Nash
The applicant begins with the Edgecombe and Nash County patient population as of December 31, 2020.	76	32
The applicant projects the Edgecombe and Nash patient populations forward for one year to December 31, 2021, using the Five-Year AACR for each of the respective counties [3.8% and 1.2% respectively].	$76 \times 1.038 = 78.9$	$32 \times 1.012 = 32.4$
The applicant projects the Edgecombe and Nash patient populations forward for one year to December 31, 2022, using the Five-Year AACR for each of the respective counties [3.8% and 1.2% respectively].	$78.9 \times 1.038 = 81.9$	$32.4 \times 1.012 = 32.8$
Subtract 27 Edgecombe County patients projected to transfer to FKC Boice-Willis	$81.9 - 27 = 54.9$	32.8
The applicant projects the Edgecombe and Nash patient populations forward for one year to December 31, 2023, using the Five-Year AACR for each of the respective counties [3.8% and 1.2% respectively].	$54.9 \times 1.038 = 56.9$	$32.8 \times 1.012 = 33.2$
The applicant totals the Edgecombe and Nash projected patients and adds the 4 patients from Halifax and Wilson Counties. This is the projected ending census for <b>Operating Year 1 (CY2023)</b> .	$56.9 + 33.2 + 3 + 1 = 94.1$	
The applicant projects the Edgecombe and Nash patient populations forward for one year to December 31, 2024, using the Five-Year AACR for each of the respective counties [3.8% and 1.2% respectively].	$56.9 \times 1.038 = 59.1$	$33.2 \times 1.012 = 33.6$
The applicant totals the Edgecombe and Nash projected patients and adds the 4 patients from Halifax and Wilson Counties. This is the projected ending census for <b>Operating Year 1 (CY2024)</b> .	$59.1 + 33.6 + 3 + 1 = 96.7$	

Therefore, at the end of OY1 (CY2023) the facility is projected to serve 94.1 in-center patients and at the end of OY2 (CY2024) the facility is projected to serve 96.7 in-center patients.

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

- OY1: 3.14 patients per station per week or 78.50% utilization ( $94.1 \text{ patients} / 30 \text{ stations} = 3.14$ ;  $3.14/4 = 0.785$  or 78.50%)
- OY2: 3.22 patients per station per week or 80.5% utilization ( $96.7 \text{ patients} / 30 \text{ stations} = 3.22$ ;  $3.22/4 = 0.805$  or 80.5%)

The projected utilization of 3.14 patients per station per week at the end of OY1 exceeds the minimum standard of 2.8 in-center patients per station per week required by 10A NCAC 14C .2203(b).

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

- The applicant projects future utilization based on the most recent historical patient census.
- The applicant applied a projected annual growth rate of 3.8% for the patients from Edgecombe County and 1.2% for the patients from Nash County based on each counties respective Five-Year AACRs as published in the 2021 SMFP.
- The applicant does not project growth for its patients who do not reside in either Edgecombe or Nash County.
- The applicant accounted for the projected 27 Edgecombe patients to transfer their care to FKC-Boice-Willis as of December 31, 2022.
- Projected utilization for the in-center patients at the end of OY1 exceeds the minimum of 2.8 patients per station per week required by 10A NCAC 14C .2203(b).
- The project is scheduled to begin offering services on December 31, 2022. OY1 is CY 2023. OY2 is CY 2024.

**Access to Medically Underserved Groups**

In Section C.6, page 33, the applicant states:

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

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

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

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

<b>Medically Underserved Groups</b>	<b>Percentage of Total Patients</b>
Low income persons	62.6%
Racial and ethnic minorities	97.4%
Women	50.4%
Persons with Disabilities	89.6%
Persons 65 and older	40.9%
Medicare beneficiaries	48.7%
Medicaid recipients	60.9%

Source: Section C, page 33.

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

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

### **Conclusion**

The Agency reviewed the:

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

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

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

### **C**

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 30 stations at BMA East Rocky Mount upon completion of this project and Project ID #L-12135-21 (relocate 6 to FKC Boice-Willis).

In Section E.2, page 41, the applicant describes the alternatives considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the identified need. The alternatives considered were:

- *Maintain the Status Quo* - The applicant states that maintaining the status quo is not an effective alternative because this alternative fails to account for the growing patient population in the area of the BMA East Rocky Mount facility and could result in patients being denied care in a convenient setting.
- *Add more than six stations* – The applicant states that adding more than six stations is not cost-effective because the BMA East Rocky Mount facility does not have adequate capacity to accommodate more than six additional stations and would require significant capital expenditure to develop additional space.
- *Add fewer than four stations* – The applicant states that adding fewer than six stations is less effective because it fails to recognize the growing patient population in the area of the BMA East Rocky Mount facility and would mean that ultimately some patients could be denied dialysis at BMA East Rocky Mount due to lack of capacity.

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

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides reasonable information to explain why they believe the proposed project is the most effective alternative.

### **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 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. The certificate holder shall develop no more than six in-center stations for a total of no more than 30 stations at BMA East Rocky Mount upon completion of this project and Project ID #L-12135-21 (relocate 6 to FKC Boice-Willis).**
- 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 October 1, 2022. The second progress report shall be due on January 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 30 stations at BMA East Rocky Mount upon completion of this project and Project ID #L-12135-21 (relocate 6 to FKC Boice-Willis).

### **Capital and Working Capital Costs**

In Section F.1, page 42, and Section Q Form F.1a Capital Cost, page 86, the applicant projects there will be no capital cost associated with the project.

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

	<b>1<sup>st</sup> Full Fiscal Year (CY2023)</b>	<b>2<sup>nd</sup> Full Fiscal Year (CY2024)</b>
Total Treatments	13,749	14,122
Total Gross Revenues (Charges)	\$86,494,184	\$88,841,329
Total Net Revenue	\$3,727,123	\$3,828,264
Average Net Revenue per Treatment	\$271.08	\$271.09
Total Operating Expenses (Costs)	\$3,722,033	\$3,797,453
Average Operating Expense per Treatment	\$270.71	\$268.90
Net Income	\$5,090	\$30,811

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:

- The applicant adequately explains the assumptions used to project revenue, such as projected reimbursement rates, and operating costs, such as salaries.
- Charges and expenses are based on historical facility operations projected forward.
- Payor percentages are based on historical facility operations.
- FTEs and salaries are based on current staffing and projected to average annual salary increases of 2.0%
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application.

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

- The applicant adequately demonstrates 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.

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 30 stations at BMA East Rocky Mount upon completion of this project and Project ID #L-12135-21 (relocate 6 to FKC Boice-Willis).

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.”* BMA East Rocky Mount is in Edgecombe County. Thus, the service area for this application is Edgecombe County. Facilities may serve residents of counties not included in their service area.

Currently, there are four existing and approved dialysis facilities in Edgecombe County, three of which are owned by BMA, as shown in the following table:

<b>Edgecombe County Dialysis Facilities Certified Stations and Utilization as of December 31, 2019</b>				
<b>Dialysis Facility</b>	<b>Owner</b>	<b>Location</b>	<b># of Certified Stations</b>	<b>Utilization</b>
BMA East Rocky Mount	BMA	Rocky Mount	30	95.00%
Fresenius Medical Clinic Tarboro*	BMA	Tarboro	10	102.50%
Fresenius Kidney Care Boice-Willis**	BMA	Rocky Mount	0	0.00%
Dialysis Care of Edgecombe County	DaVita	Tarboro	35	39.29%

Source: 2021 SMFP, Table 9A, pages 122-123.

\*On April 3, 2020, Fresenius Medical Clinic Tarboro (FMC Tarboro) received conditional approval to relocate no more than 4 dialysis stations from BMA East Rocky Mount to FMC Tarboro for a total of no more than 14 stations at FMC Tarboro upon project completion. See Project I.D.#L-11839-20. This project received its Certificate of Need with an effective date of May 5, 2020. The facility is currently certified for 14 stations.

\*\*On November 28, 2017 this project received a Certificate of Need to develop a new 10-station dialysis facility by relocating 10 stations from BMA East Rocky Mount. The project was not complete as of December 31, 2019 and has only been operating a short time as of 12/31/2020.

In Section G, page 49, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Edgecombe County. The applicant states that this application is based upon facility performance and demonstrated need at BMA East Rocky Mount and is not specific to Edgecombe County as a whole. The applicant states:

*“This is an application based upon the facility performance and demonstrated need at BMA East Rocky Mount. The need addressed by this application is not specific to Edgecombe County as a whole.*

*...of the four facilities with in-center stations, two BMA facilities are operating in excess of 80% utilization. The FKC Boice-Willis facility was a new facility and has only been operating a very short time. ... BMA cannot speak to utilization of the DaVita facility in Tarboro. Moreover, Tarboro is not proximate to the Rocky Mount area. It is approximately 16 miles, or 20 minutes, from Rocky Mount to Tarboro.”*

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 BMA East Rocky Mount needs the additional stations as proposed to serve its existing and projected patient population.
- The applicant adequately demonstrates that the proposed addition of six dialysis stations is needed at the facility and would have no adverse impact on the existing and approved stations in Edgecombe County as a whole.

### **Conclusion**

The Agency reviewed the:

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

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

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

### **C**

The applicant proposes to add no more than six dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 30 stations at BMA East Rocky Mount upon completion of this project and Project ID #L-12135-21 (relocate 6 to FKC Boice-Willis).

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

POSITION	Current FTE Positions (9/15/2021)	FTE POSITIONS OY1 (CY2023)	FTE POSITIONS OY2 (CY2024)
Administrator	1.00	1.00	1.00
RN	6.00	6.00	6.00
Patient Care Technician (PCT)	11.00	11.00	11.00
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	1.5	1.5	1.5
FMC Director Operations	0.15	0.15	0.15
FMC Chief Technician	0.15	0.15	0.15
FMC In-Service	0.15	0.15	0.15
<b>Total</b>	<b>22.95</b>	<b>22.95</b>	<b>22.95</b>

Source: Section Q Form H, page 96.

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.4. In Section H.2 and H.3, pages 51-52, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

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

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

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

## 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 30 stations at BMA East Rocky Mount upon completion of this project and Project ID #L-12135-21 (relocate 6 to FKC Boice-Willis).

### **Ancillary and Support Services**

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

- The applicant currently provides dialysis services at BMA East Rocky Mount with the necessary ancillary and support services.
- The applicant states that it has agreements in place for lab services, hospital affiliation, and transplant services.

### **Coordination**

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

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

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

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

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

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

NA

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

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

NA

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

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and ... persons [with disabilities], which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs

identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

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

**C**

In Section L, page 66, the applicant provides the historical payor mix for in-center dialysis during CY2020 for BMA East Rocky Mount, as summarized in the table below.

Primary Payor Source at Admission	In-center Dialysis	
	# of Patients	% of Total
Self-Pay	0.3	0.3%
Insurance *	3.5	3.1%
Medicare *	93.2	83.2%
Medicaid *	10.1	9.0%
Other (VA and Misc.)	4.9	4.4%
<b>Total</b>	<b>112.0</b>	<b>100.0%</b>

\*Including any managed care plans

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

**BMA East Rocky Mount**

	Percentage of Total Patients Served	Percentage of the Population of the Service Area
Female	50.0%	53.8%
Male	50.0%	46.2%
Unknown		
64 and Younger	59.5%	79.6%
65 and Older	40.5%	20.4%
American Indian	0.9%	0.8%
Asian	0.0%	0.3%
Black or African American	94.8%	57.8%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	2.6%	36.0%
Other Race	1.7%	5.0%
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 67, the applicant states it has no such obligation.

In Section L.2, page 67, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against BMA East Rocky Mount.

### Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

### C

In Section L.3, page 68, 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.

Primary Payor Source at Admission	In-center Dialysis	
	# of Patients	% of Total
Self-Pay	0.3	0.3%
Insurance *	3.0	3.1%
Medicare *	80.4	83.2%
Medicaid *	8.7	9.0%
Other (VA and Misc.)	4.2	4.4%
Total	96.7	100.0%

\*Including any managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 0.3% of BMA East Rocky Mount's dialysis services will be provided to self-pay patients, 83.2% to Medicare recipients and 9.0% to Medicaid recipients.

On page 68, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- The applicant 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, pages 69-70, the applicant adequately describes the range of means by which patients will have access to the proposed services.

### Conclusion

The Agency reviewed the:

- Application

- Exhibits to the application

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

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

## C

The applicant proposes to add no more than six dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 30 stations at BMA East Rocky Mount upon completion of this project and Project ID #L-12135-21 (relocate 6 to FKC Boice-Willis).

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

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

## Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (15) Repealed effective July 1, 1987.  
(16) Repealed effective July 1, 1987.  
(17) Repealed effective July 1, 1987.  
(18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case

of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

**C**

The applicant proposes to add no more than six dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 30 stations at BMA East Rocky Mount upon completion of this project and Project ID #L-12135-21 (relocate 6 to FKC Boice-Willis).

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

Currently, there are four existing and approved dialysis facilities in Edgecombe County, three of which are owned by BMA, as shown in the following table:

<b>Edgecombe County Dialysis Facilities Certified Stations and Utilization as of December 31, 2019</b>				
<b>Dialysis Facility</b>	<b>Owner</b>	<b>Location</b>	<b># of Certified Stations</b>	<b>Utilization</b>
BMA East Rocky Mount	BMA	Rocky Mount	30	95.00%
Fresenius Medical Clinic Tarboro*	BMA	Tarboro	10	102.50%
Fresenius Kidney Care Boice-Willis**	BMA	Rocky Mount	0	0.00%
Dialysis Care of Edgecombe County	DaVita	Tarboro	35	39.29%

Source: 2021 SMFP, Table 9A, pages 122-123.

\*On April 3, 2020, Fresenius Medical Clinic Tarboro (FMC Tarboro) received conditional approval to relocate no more than 4 dialysis stations from BMA East Rocky Mount to FMC Tarboro for a total of no more than 14 stations at FMC Tarboro upon project completion. See Project I.D.#L-11839-20. This project received its Certificate of Need with an effective date of May 5, 2020. The facility is currently certified for 14 stations.

\*\*On November 28, 2017 this project received a Certificate of Need to develop a new 10-station dialysis facility by relocating 10 stations from BMA East Rocky Mount. The project was not complete as of December 31, 2019 and has only been operating a short time as of 12/31/2020.

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

*“The applicant does not expect this proposal to have any effect on the competitive climate in Edgecombe County. The applicant does not project to serve dialysis patients currently being served by another provider.”*

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

*“Approval of this application will allow the facility to serve patients of the area in a convenient setting. As a result, these patients will have a shorter commute to and from dialysis treatment. This is an immediate and significantly positive impact to the patients of the area.”*

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

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

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

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

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 73, 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.”*

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

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

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

## **Conclusion**

The Agency reviewed the:

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

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

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

### **C**

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

In Section O, page 78, the applicant states that, during the 18 months immediately preceding the submittal of the application, no Fresenius related facility has been found to have had an incident related to quality of care that resulted in a finding of “*Immediate Jeopardy*.” After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all Fresenius facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

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

### **C**

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

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

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

-NA- The applicant does not propose to establish a new kidney disease treatment center or dialysis facility. Therefore, this Rule is not applicable to this review.

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

(1) *an existing dialysis facility; or*

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

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

-C- In Section C, pages 27-28, and in Section Q Form C Utilization, the applicant projects that BMA East Rocky Mount will serve 94.1 in-center patients on 30 stations, a utilization rate of 3.14 ( $94.1 / 30 = 3.14$ ;  $3.14/4 = 0.785$  or 78.50%) patients per station per week, as of the end of the first operating year following project completion, meeting 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 25-28, and in the Form C Utilization subsection of Section Q, the applicant provides the assumptions and methodology it uses to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.