

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: February 24, 2021

Findings Date: February 24, 2021

Project Analyst: Gregory F. Yakaboski

Co-Signer: Micheala L. Mitchell

Project ID #: F-12134-21

Facility: BMA Kings Mountain

FID #: 150476

County: Gaston

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

Project: Relocate no more than four dialysis stations from Fresenius Medical Care Gastonia for a total of no more than 26 stations upon project completion

REVIEW CRITERIA

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

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

C

Bio-Medical Applications of North Carolina, Inc. (hereinafter "BMA" or "the applicant") proposes to relocate four dialysis stations from Fresenius Medical Care Gastonia (FMC Gastonia) to BMA Kings Mountain. Upon project completion BMA Kings Mountain will have 26 stations and FMC Gastonia will have 35 stations.

BMA Kings Mountain, during its last full FY (CY2020), provided in-center (IC) dialysis and a home hemodialysis (HH) program, however, at that time the facility did not provide a peritoneal dialysis (PD) program. Fresenius Medical Care Holdings, Inc. (Fresenius) is the ultimate parent company of BMA.

The applicant does not propose to:

- Develop any beds or services for which there is a need determination in the 2021 State Medical Facilities Plan (SMFP).
- Offer a new institutional health service for which there are any policies in the 2021 SMFP.

Therefore, Criterion (1) is not applicable to this review.

- (2) Repealed effective July 1, 1987.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 relocate four dialysis stations from FMC Gastonia to BMA Kings Mountain. Upon project completion BMA Kings Mountain will have 26 stations and FMC Gastonia will have 35 stations.

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 area: Cherokee, Clay, and Graham counties and Avery, Mitchell, and Yancey counties.” BMA Kings Mountain is in Gaston County. Thus, the service area for this application is Gaston County. Facilities may serve residents of counties not included in their service area.

The following table illustrates historical and projected patient origin at BMA Kings Mountain.

BMA Kings Mountain: Current & Projected Patient Origin												
County	Current – CY 2020						Projected – CY 2024					
	IC Patients		HH Patients		PD Patients		IC* Patients		HH Patients		PD Patients	
	#	%	#	%	#	%	#	%	#	%	#	%
Gaston	22	34.92%	1	14.30%	0	0.00%	25.4	33.20%	0	0.00%	2.2	65.70%
Cherokee	0	0.00%	1	14.3%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
Cleveland	38	60.32%	2	28.6%	0	0.00%	48.9	63.90%	3.4	50.70%	1.1	34.30%
Lincoln	2	3.17%	0	0.00%	0	0.00%	1	1.40%	0	0.00%	0	0.00%
Mecklenburg	1	1.59%	1	14.3%	0	0.00%	1	1.40%	0	0.00%	0	0.00%
Rutherford	0	0.00%	1	14.3%	0	0.00%	0	0.00%	1	16.40%	0	0.00%
South Carolina	0	0.00%	1	14.3%	0	0.00%	0	0.00%	2	32.90%	0	0.00%
Total	63	100.00%	7	100.00%	0	100.00%	76.4	100.00%	6.8	100.00%	3.3	100.00%

Note: Table may not foot due to rounding.

Source: Section C, pages 23-24.

In Section C.3, pages 24-31, 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 clearly explains how and why growth was projected in the Gaston and Cleveland County patient populations.
- The applicant did not project any growth in patients dialyzing at BMA Kings Mountain who resided outside either of Gaston or Cleveland County.
- Projected growth in patients residing in either Gaston or Cleveland County is based on the historical patient origin for in-center dialysis patients for BMA Kings Mountain as of August 1, 2021.

Analysis of Need

In Section C.3, pages 24-26, the applicant describes its need methodology and assumptions for projecting in-center utilization of the facility, summarized as follows:

- The applicant states that it projects patients forward from the August 1, 2021 census data. The applicant states that it assumes the patients from Gaston and Cleveland Counties dialyzing at BMA Kings Mountain on August 1, 2021 will continue to dialyze there and will increase at a rate equal to the Gaston and Cleveland Counties Five Year Average Annual Change Rate (AACR) of 2.9% and 3.8% respectively, as published in the 2021 SMFP.
- The applicant assumes the patients from Lincoln and Mecklenburg Counties will continue to dialyze at BMA Kings Mountain but does not assume any growth in patients from those counties.
- The project is scheduled for completion on December 31, 2022. Therefore, Operating Year (OY) 1 is calendar year (CY) 2023, January 1-December 31, 2023 and OY2 is CY2024, January 1-December 31, 2024.

Projected Utilization

In-Center Utilization

In Section C, page 26, and Section Q, Form C, the applicant provided the methodology used to project in-center utilization, as illustrated in the following table.

	Gaston	Cleveland
The applicant begins with the Gaston and Cleveland County patient population as of August 1, 2021.	23	43
The applicant projects these patient populations forward for five months to December 31, 2021, using the Five-Year AACR for each of the respective counties [2.9% and 3.8% respectively].	$23 \times (.029/12 \times 5) + 23 = 23.3$	$43 \times (.038/12 \times 5) + 43 = 43.7$
The applicant projects these patient populations forward for one year to December 31, 2022, using the Five-Year AACR for each of the respective counties [2.9% and 3.8% respectively].	$23.3 \times 1.029 = 24.0$	$43.7 \times 1.038 = 45.3$
The applicant projects these patient populations forward for one year to December 31, 2023, using the Five-Year AACR for each of the respective counties [2.9% and 3.8% respectively].	$24.0 \times 1.029 = 24.6$	$45.3 \times 1.038 = 47.1$
The applicant totals the Gaston and Cleveland projected patients and adds the 2 patients from Lincoln and Mecklenburg Counties. This is the projected ending census for Operating Year 1 (CY2023) .	$24.6 + 47.1 + 2 = \mathbf{73.7}$	
The applicant projects these patient populations forward for one year to December 31, 2023, using the Five-Year AACR for each of the respective counties [2.9% and 3.8% respectively].	$24.6 \times 1.029 = 25.4$	$47.1 \times 1.038 = 48.9$
The applicant totals the Gaston and Cleveland projected patients and adds the 2 patients from Lincoln and Mecklenburg Counties. This is the projected ending census for Operating Year 2 (CY2024) .	$25.4 + 48.9 + 2 = \mathbf{76.4}$	

Therefore, at the end of OY1 (CY2023) the facility is projected to serve 73.7 in-center patients and at the end of OY2 (CY2024) the facility is projected to serve 76.4 in-center patients.

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

- OY1: 2.83 patients per station per week or 70.75% utilization (73.7 patients / 26 stations = 2.83; $2.83/4 = 0.7075$ or 70.75%).
- OY2: 2.94 patients per station per week or 73.50% utilization (76.4 patients / 26 stations = 2.94; $2.94/4 = 0.735$ or 73.50%).

The projected utilization of 2.83 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).

In Section C, pages 24-26 and Section Q, Form C, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The applicant projects the first two full operating years of the project will be January 1, 2023–December 31, 2023 (CY2023) and January 1, 2024–December 31, 2024 (CY2024).
- The applicant begins its projections with the facility census as of August 1, 2021 with 23 patients residing in Gaston County, 43 patients residing in Cleveland County and one patient residing in each of Lincoln and Mecklenburg Counties.
- The applicant projected annual growth for the patients residing in Gaston and Cleveland Counties at a rate equal to the Gaston and Cleveland Counties Five Year AACR of 2.9% and 3.8% respectively, as published in the 2021 SMFP.
- The applicant does not project growth for the 2 patients residing outside of either Gaston or Cleveland Counties.

Projected utilization for IC 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 2.9% for the patients from Gaston County and 3.8% for the patients from Cleveland County based on each counties respective Five-Year AACR of 2.9% and 3.8% respectively, as published in the 2021 SMFP.
- The applicant does not project growth for its IC patients who do not reside in either Gaston or Cleveland County.
- 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).

HH and PD Training

- The applicant begins its utilization projections with the HH and PD patient census at BMA Kings Mountain on August 1, 2021. The applicant states that on August 1, 2021, it was serving no Gaston or Cleveland Counties HH patients, one PD patient from Cleveland County, one HH patient from Rutherford County and two HH patients from South Carolina.
- The applicant states that as the COVID pandemic begins to wane it is re-assigning five home patients (3 HH patients and 2 PD patients) from FKC North Gaston back to BMA Kings Mountain, which is closer to their residences. This re-assignment will occur prior to December 31, 2021.
- The applicant will apply a projected annual growth rate of 2.9% for the patients from Gaston County and 3.8% for the patients from Cleveland County based on each counties respective Five-Year AACR of 2.9% and 3.8% respectively, as published in the 2021 SMFP.
- The applicant assumes no population growth for the HH patients residing in Rutherford County (1) and South Carolina (2) but assumes the patients will continue to be supported

by the home training and support program and adds them to the calculations when appropriate.

- The project is scheduled to begin offering services on December 31, 2022. OY1 is CY 2023. OY2 is CY 2024.

In Section C, pages 30-31, and immediately following Form C in Section Q, the applicant provides the calculations used to project the HH and PD patient census for OY1 and OY2, as summarized in the tables below.

HH Projected Utilization: BMA Kings Mountain

	Gaston	Cleveland
The applicant begins with the Gaston and Cleveland County patient population as of August 1, 2021.	0	0
Add the three HH patients to reassigned from FKC North Gaston as of August 1, 2021	0	3
The applicant projects these patient populations forward for one year to December 31, 2022, using the Five-Year AACR for each of the respective counties [2.9% and 3.8% respectively].	0	$3 \times 1.038 = 3.1$
The applicant projects these patient populations forward for one year to December 31, 2023, using the Five-Year AACR for each of the respective counties [2.9% and 3.8% respectively].	0	$3.1 \times 1.038 = 3.2$
The applicant totals the Gaston and Cleveland projected patients and adds the 3 patients from Rutherford County and South Carolina. This is the projected ending census for Operating Year 1 (CY2023) .	$0 + 3.2 + 3 = 6.2$	
The applicant projects these patient populations forward for one year to December 31, 2023, using the Five-Year AACR for each of the respective counties [2.9% and 3.8% respectively].	0	$3.2 \times 1.038 = 3.4$
The applicant totals the Gaston and Cleveland projected patients and adds the 3 patients from Rutherford County and South Carolina. This is the projected ending census for Operating Year 2 (CY2024) .	$0 + 3.4 + 3 = 6.4$	

PD Projected Utilization: BMA Kings Mountain

	Gaston	Cleveland
The applicant begins with the Gaston and Cleveland County patient population as of August 1, 2021.	0	0
Project the respective County patient populations forward for 5 months to December 31, 2022	0	$1 \times (0.038/12 \times 5) + 1 = 1.02$
Add the two PD patients to reassigned from FKC North Gaston as of December 31, 2021	2	1.02
The applicant projects these patient populations forward for one year to December 31, 2022, using the Five-Year AACR for each of the respective counties [2.9% and 3.8% respectively].	$2 \times 1.029 = 2.06$	$1.02 \times 1.038 = 1.05$
The applicant projects these patient populations forward for one year to December 31, 2023, using the Five-Year AACR for each of the respective counties [2.9% and 3.8% respectively].	$2.06 \times 1.029 = 2.12$	$1.05 \times 1.038 = 1.09$
The applicant totals the Gaston and Cleveland projected patients. This is the projected ending census for Operating Year 1 (CY2023) .	$2.12 + 1.09 = \mathbf{3.21}$	
The applicant projects these patient populations forward for one year to December 31, 2023, using the Five-Year AACR for each of the respective counties [2.9% and 3.8% respectively].	$2.12 \times 1.029 = 2.18$	$1.09 \times 1.038 = 1.14$
The applicant totals the Gaston and Cleveland projected patients. This is the projected ending census for Operating Year 2 (CY2024) .	$2.18 + 1.14 = \mathbf{3.32}$	

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

- The applicant projects future utilization based on historical utilization.
- The applicant will apply a projected annual growth rate of 2.9% for the patients from Gaston County and 3.8% for the patients from Cleveland County based on each counties respective Five-Year AACR of 2.9% and 3.8% respectively, as published in the 2021 SMFP.
- The applicant adds in the HH and PD patients being reassigned from FKC North Gaston.
- There has been a national emphasis on moving patients to home dialysis because it typically results in better outcomes. Because of that, more and more patients are being referred for in-home dialysis.

Access to Medically Underserved Groups

In Section C.6, page 36, 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.

Medically Underserved Groups	Percentage of Total Patients
Low income persons	37.1%
Racial and ethnic minorities	70.0%
Women	42.9%
Persons with Disabilities	15.7%
Persons 65 and older	44.3%
Medicare beneficiaries	85.7%
Medicaid recipients	35.7%

Source: Section C, page 37.

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 proposes to relocate four dialysis stations from FMC Gastonia to BMA Kings Mountain. Upon project completion BMA Kings Mountain will have 26 stations and FMC Gastonia will have 35 stations.

In Section D, pages 42-43, the applicant explains why it believes the needs of the population presently utilizing the services to be relocated will be adequately met following completion of the project. On page 43, the applicant provides a table which shows projected FMC Gastonia utilization assuming the relocation of 4 stations to the BMA Kings Mountain facility, which is summarized below:

The applicant begins with the Gaston County patient population as of December 31, 2020.	116
The applicant projects the Gaston County in-center patients forward one year to December 31, 2021 using the Gaston County Five-Year AACR.	$116 \times 1.029 = 119.4$
The applicant projects the Gaston County in-center patients forward one year to December 31, 2022 using the Gaston County Five-Year AACR.	$119.4 \times 1.029 = 122.8$
The applicant adds the seven patients from Cleveland, Lincoln and Mecklenburg Counties and South Carolina.	$122.8 + 7 = 129.8$

As shown in the table above, FMC Gastonia is projected to have a utilization rate of 3.71 patients per station per week or 92.75% ($129.8 \text{ patients} / 35 \text{ stations} = 3.71$; $3.71 / 4 = 0.9275$ or 92.75%) at the time the proposed stations will be relocated and certified at BMA Kings Mountain. The applicant states that the population presently served at FMC Gastonia will continue to have their needs adequately met by the remaining stations and proposed addition of dialysis stations in 2021. On page 43, the applicant states:

“As an additional consideration, BMA notes that the 2021 SMFP, Table 9D indicates that FMC Gastonia qualifies to apply for up to four additional stations in 2021. The facility has not yet applied for any Facility Need stations. BMA will apply for four dialysis stations at FMC Gastonia in November 2021, for the ESRD review to commence on December 1, 2021.

No patients will be adversely affected by approval of this application to relocate dialysis stations from BMA Gastonia to BMA Kings Mountain.”

In Section D.3, pages 43-44, the applicant states the relocation of four stations from FMC Gastonia to BMA Kings Mountain will not have any impact on the access to services by low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, Medicare beneficiaries or Medicaid recipients.

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 needs of the population currently using the services to be relocated will be adequately met following project completion.
- The project will not adversely impact the ability of underserved groups to access these services following project completion.

- (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 relocate four dialysis stations from FMC Gastonia to BMA Kings Mountain. Upon project completion BMA Kings Mountain will have 26 stations and FMC Gastonia will have 35 stations.

In Section E.2, page 46, 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 Kings Mountain facility.
- *Relocate more than four stations* – The applicant states that relocating more than four stations is not cost-effective because the BMA Kings Mountain facility does not have adequate capacity to accommodate more than four stations and would require significant capital expenditure to develop additional space.
- *Relocate fewer than four stations* – The applicant states that relocating fewer than four stations is less effective because it fails to recognize the growing patient population in the area of the BMA Kings Mountain facility and would mean that ultimately some patients could be denied dialysis at BMA Kings Mountain 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 relocate four stations from FMC Gastonia to BMA Kings Mountain for a total of no more than 26 in-center and home hemodialysis stations at BMA Kings Mountain upon completion of this project.**
- 3. Upon completion of this project, the certificate holder shall take the necessary steps to decertify four stations at FMC Gastonia for a total of no more than 35 in-center and home hemodialysis stations at FMC Gastonia upon completion of this project.**
- 4. 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 third month. The first progress report shall be due on July 1, 2022. The second progress report shall be due on October 1, 2022 and so forth.

5. 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 relocate four dialysis stations from FMC Gastonia to BMA Kings Mountain. Upon project completion BMA Kings Mountain will have 26 stations and FMC Gastonia will have 35 stations.

Capital and Working Capital Costs

In Section Q Form F.1a Capital Cost, page 98, the applicant projects the total capital cost of the project, as summarized below.

Site Costs	\$0
Construction Costs	\$0
Furniture /Fixtures Costs	\$15,000
Total	\$15,000

In Section Q, page 98, 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.

In Sections F.3, page 49, 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 47, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	Bio-Medical Applications of North Carolina, Inc.
Loans	\$0
Cash Equivalents, Accumulated reserves or OE *	\$15,000
Bonds	\$0
Other (Specify)	\$0
Total Financing	\$15,000

* OE = Owner’s Equity

Exhibit F-2 contains a letter dated September 15, 2021 from the Senior Vice President and Treasurer, authorizing and committing accumulated reserves of Fresenius Medical Care Holdings Inc., the parent company for BMA, for the 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.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

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.

	1 st Full Fiscal Year (CY2023)	2 nd Full Fiscal Year (CY2024)
Total Treatments	12,125	12,531
Total Gross Revenues (Charges)	\$76,278,482	\$78,832,304
Total Net Revenue	\$3,497,111	\$3,612,483
Average Net Revenue per Treatment	\$288	\$288
Total Operating Expenses (Costs)	\$3,399,823	\$3,470,334
Average Operating Expense per Treatment	\$280	\$277
Net Income	\$97,288	\$142,149

The assumptions used by the applicant in preparation of the pro forma financial statements are provided immediately following Form F.2 and in Forms F.3 and F.4 in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following reasons:

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

C

The applicant proposes to relocate four dialysis stations from FMC Gastonia to BMA Kings Mountain. Upon project completion BMA Kings Mountain will have 26 stations and FMC Gastonia will have 35 stations.

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

According to Table 9A of the 2021 SMFP, there are five existing dialysis facilities in Gaston County, all of which are owned and operated by Fresenius. Information on these dialysis facilities, from Table 9A of the 2021 SMFP, is provided below:

Edgecombe County Dialysis Facilities Certified Stations and Utilization as of December 31, 2019				
Dialysis Facility	Owner	Location	# of Certified Stations	Utilization
BMA Kings Mountain	Fresenius	Kings Mountain	21	70.24%
FKC North Gaston*	Fresenius	Dallas	12	68.75%
FMC Belmont	Fresenius	Belmont	19	82.89%
FMC Gastonia	Fresenius	Gastonia	39	87.18%
FMC South Gaston	Fresenius	Gastonia	28	74.11%

Source: 2021 SMFP, Chapter 9, Table 9A, page 123.

*Designated as both a new facility and a small facility according to Condition 1.a of the facility need determination of the SMFP.

In Section G, page 54, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Gaston County. The applicant states:

“The applicant proposes to relocate existing certified dialysis stations within Gaston County. These stations have been previously approved and do not duplicate services.”

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 reasons:

- The applicant does not propose to increase the number of certified dialysis stations in Gaston County.
- The applicant adequately demonstrates that the proposed relocation of dialysis stations within Gaston County from FMC Gaston to BMA Kings Mountain is needed in addition to the existing or approved dialysis stations in Gaston County.

Conclusion

The Agency reviewed the:

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

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

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

The applicant proposes to relocate four dialysis stations from FMC Gastonia to BMA Kings Mountain. Upon project completion BMA Kings Mountain will have 26 stations and FMC Gastonia will have 35 stations.

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

POSITION	Current FTE Positions (7/15/2021)	FTE POSITIONS OY1 (CY2023)	FTE POSITIONS OY2 (CY2024)
Administrator	1.00	1.00	1.00
RN	3.00	3.00	3.00
Home Training Nurse	1.00	2.00	2.00
Patient Care Technician (PCT)	5.00	5.00	5.00
Dietician	0.50	0.50	0.50
Social Worker	0.50	0.50	0.50
Maintenance	2.00	2.00	2.00
Administration/Business Office	5.00	5.00	5.00
FMC Director Operations	0.15	0.15	0.15
FMC Chief Technician	0.10	0.10	0.10
FMC In-Service	0.10	0.10	0.10
Total	18.35	19.35	19.35

Source: Section Q Form H, page 108.

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 56-57, 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 relocate four dialysis stations from FMC Gastonia to BMA Kings Mountain. Upon project completion BMA Kings Mountain will have 26 stations and FMC Gastonia will have 35 stations.

Ancillary and Support Services

In Section I, page 58, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 58-63, 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 Kings Mountain 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 63, 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, pages 71-72, the applicant provides the historical payor mix during CY 2020 for the proposed services for both BMA Kings Mountain and FMC Gastonia, as shown in the tables below.

BMA Kings Mountain: Historical Payor Mix CY 2020						
Payment Source	In-Center		HH		PD	
	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients
Self-Pay	0.1	0.17%	0.0	0.00%	0.0	0.00%
Insurance*	2.8	4.52%	0.2	2.97%	0.0	38.30%
Medicare*	54.8	87.06%	6.8	97.03%	0.0	61.70%
Medicaid*	1.7	2.70%	0.0	0.00%	0.0	0.00%
Misc. (including VA, Med. Adv.)	3.5	5.55%	0.0	0.00%	0.0	0.00%
Total	63	100.00%	7.0	100.00%	0.0	100.00%

*Including any managed care plans
 Source: Table on page 71.

FMC Gastonia: Historical Payor Mix CY 2020						
Payment Source	In-Center		HH		PD	
	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients
Self-Pay	1.7	1.34%	0.6	3.02%	0.0	0.00%
Insurance*	9.5	7.71%	3.5	18.67%	3.3	27.30%
Medicare*	99.6	81.00%	14.6	76.59%	7.5	62.67%
Medicaid*	8.5	6.92%	0.3	1.56%	0.4	3.34%
Misc. (including VA, Med. Adv.)	3.7	3.03%	0.0	0.16%	0.8	6.69%
Total	123	100.00%	19.0	100.00%	12.0	100.00%

*Including any managed care plans
 Source: Table on page 72.

In Section L, pages 72-73, the applicant provides the following comparison.

BMA Kings Mountain

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY2020	Percentage of the Population of the Service Area
Female	42.90%	51.70%
Male	57.10%	48.30%
Unknown		
64 and Younger	55.70%	83.70%
65 and Older	44.30%	16.30%
American Indian	1.43%	0.60%
Asian	2.90%	1.60%
Black or African American	58.60%	17.90%
Native Hawaiian or Pacific Islander	0.00%	0.10%
White or Caucasian	37.10%	71.1%
Other Race	0.00%	8.70%
Declined / Unavailable	0.00%	

FMC Gastonia

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY2020	Percentage of the Population of the Service Area
Female	45.50%	51.70%
Male	54.40%	48.30%
Unknown		
64 and Younger	60.40%	83.70%
65 and Older	39.60%	16.30%
American Indian	0.00%	0.60%
Asian	0.75%	1.60%
Black or African American	52.20%	17.90%
Native Hawaiian or Pacific Islander	0.00%	0.10%
White or Caucasian	40.3%	71.1%
Other Race	6.70%	8.70%
Declined / Unavailable	0.00%	

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 73, the applicant states it has no such obligation.

In Section L.2, page 73, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against BMA Kings Mountain.

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, page 74, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation (CY2024) following completion of the project, as shown in the table below.

BMA Kings Mountain: Projected Payor Mix (CY 2024)						
Payment Source	In-Center		HH		PD	
	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients
Self-Pay	0.1	0.17%	0.2	3.02%	0.0	0.00%
Insurance*	3.5	4.52%	1.2	18.67%	0.9	27.30%
Medicare*	66.5	87.06%	4.9	76.59%	2.1	62.67%
Medicaid*	2.1	2.70%	0.1	1.56%	0.1	3.34%
Misc. (including VA, Med. Adv.)	4.2	5.55%	0.0	0.16%	0.2	6.69%
Total	76.4	100.00%	6.4	100.00%	3.3	100.00%

*Including any managed care plans
 Source: Table on page 74.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that for in-center services 0.71% will be provided to self-pay patients, 87.06% to Medicare patients and 2.70% to Medicaid patients.

On page 74, 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 reasons:

- The projected payor mix is based on the historical treatment volumes at BMA Kings Mountain.
- Projections assume that there will be no changes to the payor mix as a result of this project.

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 76, 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 relocate four dialysis stations from FMC Gastonia to BMA Kings Mountain. Upon project completion BMA Kings Mountain will have 26 stations and FMC Gastonia will have 35 stations.

In Section M, page 77, 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 Gaston 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 relocate four dialysis stations from FMC Gastonia to BMA Kings Mountain. Upon project completion BMA Kings Mountain will have 26 stations and FMC Gastonia will have 35 stations.

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

According to Table 9A of the 2021 SMFP, there are five existing dialysis facilities in Gaston County, all of which are owned and operated by Fresenius. Information on these dialysis facilities, from Table 9A of the 2021 SMFP, is provided below:

Edgecombe County Dialysis Facilities Certified Stations and Utilization as of December 31, 2019				
Dialysis Facility	Owner	Location	# of Certified Stations	Utilization
BMA Kings Mountain	Fresenius	Kings Mountain	21	70.24%
FKC North Gaston*	Fresenius	Dallas	12	68.75%
FMC Belmont	Fresenius	Belmont	19	82.89%
FMC Gastonia	Fresenius	Gastonia	39	87.18%
FMC South Gaston	Fresenius	Gastonia	28	74.11%

Source: 2021 SMFP, Chapter 9, Table 9A, page 123.

*Designated as both a new facility and a small facility according to Condition 1.a of the facility need determination of the SMFP.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 78, the applicant states:

“The applicant does not expect this proposal to have any effect on the competitive climate in Gaston 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 79, 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 79, 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 79, 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 84, 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, page 26, and in Section Q Form C Utilization, the applicant projects that BMA Kings Mountain will serve 73.7 in-center patients on 26 stations, a utilization rate of 2.83 ($73.7 / 26 = 2.83$) 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 23-26, 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.