

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: March 4, 2019

Findings Date: March 4, 2019

Project Analyst: Ena Lightbourne

Team Leader: Gloria C. Hale

Project ID #: F-11635-18

Facility: BMA Kings Mountain

FID #: 150476

County: Gaston

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

Project: Relocate three dialysis stations from FMC Belmont to BMA Kings Mountain for a total of 21 stations at BMA Kings Mountain

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio- Medical Applications of North Carolina, Inc. d/b/a BMA Kings Mountain proposes to relocate three dialysis stations from FMC Belmont to BMA Kings Mountain for a total of 21 dialysis stations at BMA Kings Mountain.

Need Determination

The county and facility need methodologies in the July 2018 Semiannual Dialysis Report (SDR) and the 2018 State Medical Facilities Plan (SMFP) are not applicable to this review.

Policies

There is one policy in the 2018 SMFP applicable to this review: *Policy ESRD-2: Relocation of Dialysis Stations*, on page 27.

Policy ESRD-2

Policy ESRD-2 states:

“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties. Certificate of need applicants proposing to relocate dialysis stations to a contiguous county shall:

- 1. Demonstrate that the facility losing dialysis stations or moving to a contiguous county is currently serving residents of that contiguous county; and*
- 2. Demonstrate that the proposal shall not result in a deficit, or increase an existing deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*
- 3. Demonstrate that the proposal shall not result in a surplus, or increase an existing surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.”*

BMA Kings Mountain and FMC Belmont are both located in Gaston County. Therefore, the proposed project is in compliance with Policy ESRD-2.

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 because the applicant adequately demonstrates that the proposal is consistent with Policy ESRD-2. The three dialysis stations are being relocated from FMC Belmont to BMA Kings Mountain. Both facilities are in the same county, Gaston County.

- (2) Repealed effective July 1, 1987.

- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

BMA proposes to relocate three dialysis stations from FMC Belmont to BMA Kings Mountain for a total of 21 dialysis stations at BMA Kings Mountain.

Patient Origin

On page 365, the 2018 SMFP defines the service area for dialysis stations as “a dialysis station’s service area is the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.” Thus, the service area for this facility consists of Gaston County. Facilities may also serve residents of counties not included in their service area.

In Section C.8, page 19, the applicant provides the historical patient origin for BMA Kings Mountain patients as of June 1, 2018, as shown in the table below.

**BMA Kings Mountain
 Patient Origin June 1, 2018**

County of Residence	# of In-Center Dialysis Patients	# of Home Hemo Dialysis Patients	# of PD Dialysis Patients
Gaston	27	0	1
Burke	0	0	1
Cleveland	31	1	5
Lincoln	1	0	0
Mecklenburg	0	1	1
Rutherford	0	0	1
Other States	1	0	0
Total	60	2	9

Source: Section C, page 19

The following table illustrates projected patient origin for the first two years of operation following project completion, as provided in Section C, page 13.

**BMA Kings Mountain
 Projected Patient Origin**

County	Operating Year 1 (CY2020)			Operating Year 2 (CY2021)			% of Total*	
	In-Center	HH	PD	In-Center	HH	PD	Year 1	Year 2
Gaston	31.2	0.0	1.1	33.1	0.0	1.2	40.8%	41.1%
Burke	0.0	0.0	1.0	0.0	0.0	1.0	1.3%	1.2%
Cleveland	35.9	1.0	5.1	38.0	1.0	5.1	52.9%	52.9%
Lincoln	1.0	0.0	0.0	1.0	0.0	0.0	1.3%	1.2%
Mecklenburg	0.0	1.0	1.0	0.0	1.0	1.0	2.5%	2.4%
Rutherford	0.0	0.0	1.0	0.0	0.0	1.0	1.3%	1.2%
Total	68.1	2.0	9.0	72.2	2.0	9.0	100.0%	100.0%

*Totals may not foot due to rounding

In Section C, pages 13-16, the applicant provides the assumptions and methodology it used to project patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.2, page 17, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. In Section C, pages 13-15, the applicant describes its need methodology assumptions for projecting utilization of the proposed facility as follows:

- The applicant projects the first two full operating years of the project will be January 1, 2020-December 31, 2020 (CY2020) and January 1, 2021-December 31, 2021 (CY2021).
- As of June 30, 2018, the current patient census at BMA Kings Mountain was 60 in-center patients.
- The applicant applies a growth rate based on the increasing Gaston and Cleveland County patient census. The applicant states the facility census has historically been comprised of both counties.
- The applicant uses a conservative growth rate of 6.0% based on BMA Kings Mountain’s average growth rate of 11% from 12/31/2014 to 12/31/2017 for Gaston County patients and the average growth rate of 12% from 12/31/2014 to 12/31/2017 for Cleveland County patients, as shown in the table below.

	12/31/2014	12/31/2015	12/31/2016	12/31/2017	Average % Change
Gaston	19	21	23	26	0.11031
Raw Change		2	2	3	
% Change		0.105238	0.0952	0.1304	

Source: Section C, page 14

	12/31/2014	12/31/2015	12/31/2016	12/31/2017	Average % Change
Cleveland	26	27	30	37	0.12764
Raw Change		1	3	7	
% Change		0.0385	0.1111	0.2333	

Source: Section C, page 14

- As of June 30, 2018, the current patient census for other counties at BMA Kings Mountain was one in-center patient. The applicant added this patient to the projected census at the appropriate point in time.

The information is reasonable and adequately supported for the following reasons:

- The historical patient population growth at BMA Kings Mountain.
- The applicant applies a growth rate that is more conservative than the actual growth rates of patients from Gaston and Cleveland counties.

Projected Utilization

In Section C, pages 13-16, the applicant provides its projected utilization methodology, based on its stated assumptions, as illustrated in the table below.

In-Center

BMA Kings Mountain In-Center Patients	
BMA begins with the facility census of Gaston and Cleveland County patients as of June 30, 2018	Gaston 27 Cleveland 31
Using an annual Growth Rate of 6.0%, BMA projects this census forward for six months to December 31, 2018.	Gaston $27 \times 1.03 = 27.8$ Cleveland $31 \times 1.03 = 31.9$
BMA projects this Gaston and Cleveland County patient populations forward 12 months.	Gaston $27.8 \times 1.06 = 29.5$ Cleveland $31.9 \times 1.06 = 33.8$
Add the patient from Lincoln County. This is the starting census for this project.	$29.5 + 33.8 + 1 = 64.3$
BMA projects the Gaston and Cleveland County patient populations forward for 12 months to December 31, 2020.	Gaston $29.5 \times 1.06 = 31.2$ Cleveland $33.8 \times 1.06 = 35.9$
Add the patient from Lincoln County. This is the ending census for Operating Year 1.	$31.2 + 35.9 + 1 = 68.1$
BMA Projects this Gaston and Cleveland County patient populations forward 12 months for December 31, 2021.	Gaston $31.2 \times 1.06 = 33.1$ Cleveland $35.9 \times 1.06 = 38.0$
Add the patient from Lincoln. This is the ending census for Operating Year 2.	$33.1 + 38.0 + 1 = 72.2$

Source: Table in Section C, page 15

Projected patients for OY1 and OY2 are rounded down to the nearest whole number. Therefore, at the end of OY1 (CY2020) the facility is projected to serve 68 in-center patients and at the end of OY2 (CY2021) the facility is projected to serve 72 in-center patients.

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

- OY1: 3.2380 patients per station per week 80.95% (68 patients / 21 stations = $3.2380/4 = 0.8095$ or 80.95%)
- OY2: 3.4285 patients per station per week or 85.71% (72 patients / 21 stations = $3.4285/4 = 0.8571$ or 85.71%)

The project utilization of 3.2380 patients per station per week at the end of OY1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

Home Peritoneal Dialysis (PD) and Home Hemodialysis (HH) Patients

- The applicant projects the first two full operating years of the project will be January 1, 2020– December 31, 2020 (CY2020) and January 1, 2021-December 31, 2021 (CY2021).
- The applicant begins its utilization projections by using its PD and HH patient census as of June 30, 2018.
- The applicant uses the Five-Year Average Annual Change Rate (AACR) in Table D of July 2018 SDR for Gaston County, 4.9%, and Cleveland County, 0.5%, to project the patient population forward.

In Section C, pages 13-16, the applicant provides its projected utilization methodology, based on its stated assumptions, as illustrated in the tables below.

BMA Kings Mountain HH Patients*	
	HH
BMA begins with the facility census of Gaston and Cleveland County patients as of June 30, 2018.	Gaston 0 Cleveland 1
Using one-half the annual Growth Rate of 6.0% [0.5%], BMA projects Cleveland County census forward for six months to December 31, 2018.	Cleveland 1 X 1.0025 = 1.0
BMA projects the Cleveland County patient population forward 12 months.	Cleveland 1.0 X 1.005 = 1.0
Add the patient from Mecklenburg County. This is the starting census for this project.	1.0 + 1 = 2.0
BMA projects the Cleveland County patient population forward for 12 months to December 31, 2020.	Cleveland 1.0 X 1.005 = 1.01
Add the patient from Mecklenburg County. This is the ending census for Operating Year 1.	1.01 + 1 = 2.0
BMA projects the Cleveland County patient population forward 12 months for December 31, 2021.	Cleveland 1.01 X 1.005 = 1.02
Add the patient from Mecklenburg County. This is the ending census for Operating Year 2.	1.02 + 1 = 2.02

Source: Tables in Section C, page 16

*The applicant stated 6.0% as the annual growth rate used. The actual growth rate of 0.5% for Cleveland County was used in the calculations.

BMA Kings Mountain PD Patients*	
	PD
BMA begins with the facility census of Gaston and Cleveland County patients as of June 30, 2018.	Gaston 1 Cleveland 5
Using one-half the annual Growth Rates of 6.0% [4.9%] and [0.5%] for Gaston County and Cleveland County patients, respectively, BMA projects this census forward for six months to December 31, 2018.	Gaston 1 X 1.0245 = 1.0 Cleveland 5 X 1.0025 = 5.01
BMA Projects the Gaston and Cleveland County patient populations forward 12 months.	Gaston 1 X 1.049 = 1.1 Cleveland 5 X 1.005 = 5.04
Add the patients from other counties. This is the starting census for this project.	1.1 + 5.04 + 3 = 9.14
BMA projects the Gaston and Cleveland County patient populations forward for 12 months to December 31, 2020.	Gaston 1.1 X 1.049 = 1.13 Cleveland 5.04 X 1.005 = 5.06
Add the patients from other counties. This is the ending census for Operating Year 1.	1.13 + 5.06 + 3 = 9.19
BMA Projects this Gaston and Cleveland County patient populations forward 12 months to December 31, 2021.	Gaston 1.13 X 1.049 = 1.18 Cleveland 5.06 X 1.005 = 5.09
Add the patients from other counties. This is the ending census for Operating Year 2.	1.18 + 5.09 + 3 = 9.27

Source: Tables in Section C, page 16

*The applicant stated 6.0% as annual growth rate used. The actual growth rate of 4.9% for Gaston and 0.5% for Cleveland County was used in the calculations.

Projected utilization for all patients at BMA Kings Mountain is reasonable and adequately supported for the following reasons:

- The applicant begins its utilization projections with the existing in-center, PD, and HH patient census for Gaston and Cleveland counties for BMA Kings Mountain.
- The applicant uses a conservative growth rate of 6.0% based on the average growth rate of 11% from 12/31/2014 to 12/31/2017 for Gaston County patients and the average growth rate of 12% from 12/31/2014 to 12/31/2017 for Cleveland County patients to project in-center patient utilization.
- The applicant uses the respective Five Year Average Annual Change Rates (AACR) for Gaston and Cleveland counties published in the 2018 SDR to project growth of PD and HH patients dialyzing at BMA Kings Mountain.
- The applicant adequately demonstrates the need for three additional dialysis stations at BMA Kings Mountain because projected utilization at the end of OY1 exceeds the minimum of 3.2 patients per station per week required by 10A NCAC 14C .2203(b).

Access

In Section C.3, page 17, 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 ability to pay or any other factor that would classify a patient underserved.”

In Section L.1, page 55, the applicant projects the following payor mix during the second full fiscal year of operation (CY2021) following completion of the project, as illustrated in the following table.

**BMA Kings Mountain
Projected Payor Mix CY 2021**

Payment Source	% Total Patients	% In-Center Patients	% of HH Patients	% of PD Patients
Self-pay/Indigent/Charity	1.2%	1.49%	3.93%	3.93%
Medicare	63.9%	63.89%	63.51%	63.51%
Medicaid	2.4%	2.14%	0.00%	0.00%
Commercial Insurance	10.8%	7.40%	31.92%	31.92%
Medicare/Commercial	16.9%	19.48%	0.64%	0.64%
Medicare/Medicaid	0.0%	0.00%	0.00%	0.00%
Miscellaneous (Incl. VA)	4.8%	5.61%	0.00%	0.00%
Other	0.0%	0.00%	0.00%	0.00%
Total	100.0%	100.00%	100.00%	100.00%

Source: Table in Section L, page 55

On page 55, the applicant states its assumption for projecting payor mix. The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

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

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

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

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

C

BMA proposes to relocate three dialysis stations from FMC Belmont to BMA Kings Mountain for a total of 21 dialysis stations at BMA Kings Mountain.

The following tables show the projected relocation of stations from FMC Belmont to the BMA Kings Mountain facility.

BMA Kings Mountain		
Stations	Description	Project ID #
18	Total # of existing certified stations as of the most recent SDR	
3	# of stations to be added as part of this project	F-11635-18
21	Total # of stations upon completion of all facility projects	

Source: Section A, page 4

FMC Belmont		
Stations	Description	Project ID #
19	Total # of existing certified stations as of the most recent SDR	
3	# of stations to be deleted as part of this project	F-11635-18
16	Total # of stations upon completion of all facility projects	

Source: Section A, page 4

In Section D, pages 23-24, the applicant explains why it believes the needs of the population presently utilizing the services to be reduced, eliminated or related will be adequately met following completion of the project. On pages 23-24, the applicant states:

- According to ESRD Data Collection forms submitted to DHSR, as of June 30, 2018, FMC Belmont patient census was 65 in-center patients on 19 stations. FMC Belmont does not have a home training program. FMC Belmont will net 16 stations upon completion of this project.
- The applicant projects FMC Belmont's patient census by using the Gaston County Five-Year AACR of 4.9%, as published in the July 2018 SDR.

- The applicant projects 70 in-center patients dialyzing at FMC Belmont and 16 certified dialysis stations for a utilization rate of 109.4%, or 4.38 patients per station per week ($70/16 = 4.375/4 = 1.0937$ or 109.37).
- Although FMC Belmont facility’s utilization exceeds 100%, the applicant states that the facility’s utilization rate was 85.53%, with 65 in-center patients on 19 stations as of June 30, 2018. The facility is eligible to apply for additional stations in the March 2019 application cycle. Based on the Facility Need Methodology, the facility qualifies to apply for up to three stations.

In Section D, the applicant provided projected utilization as illustrated in the following table.

FMC Belmont In-Center Patients	
	In-Center
BMA begins with the Gaston County patient census as of June 30, 2018.	55
BMA projects this census forward for six months to December 31, 2018 using one half of the Gaston County Five Year Average Annual Change Rate of 4.9%.	$55 \times 1.0245 = 56.3$
BMA projects this census forward for 12 months to December 31, 2019.	$56.3 \times 1.049 = 59.1$
Add the 10 patients from Mecklenburg County.	$59.1 + 10 = 69.1$

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

- The applicant begins its utilization projections with the existing in-center patient census of FMC Belmont as of June 30, 2018.
- The applicant uses the Five Year AACR for Gaston County as published in the 2018 SDR to project growth of in-center patients dialyzing at FMC Belmont.
- The applicant projects a utilization rate of 109.4% as of December 31, 2019, however, the utilization rate for FMC Belmont was 85.53% as of June 30, 2018. The facility qualifies to apply for additional stations based on Facility Need Methodology.

In Section D, page 26, the applicant states:

“This location of stations will not have any effect upon the ability of low income persons, racial and ethnic minorities, women, handicapped persons, the elderly and other underserved groups to obtain needed health care. Patients needing dialysis services will continue to have access to dialysis at FMC Belmont.”

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 and adequately demonstrates that:

- The needs of the population currently using the services to be reduced, eliminated or 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

BMA proposes to relocate three dialysis stations from FMC Belmont to BMA Kings Mountain for a total of 21 dialysis stations at BMA Kings Mountain.

In Section E, pages 27-28, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo. The applicant states that this is not the most effective alternative because of the growing need of patients dialyzing at BMA Kings Mountain.
- Locate Stations from other BMA Facilities in Gaston County. The applicant states that this is not the most effective alternative because all other BMA facilities in Gaston County are well utilized based on ESRD Data Collection forms submitted to DHSR for June 30, 2018. The applicant states FMC South Gaston is the only facility operating at less than 80% utilization. The facility is one patient away from exceeding 80% utilization.

The applicant states FMC Gastonia will exceed 80% utilization. The facility will be reduced from 39 stations to 37 stations upon completion of Project ID#s F-11266-16, F-11309-17 and F-11538-18.

- Move Stations to another BMA Facility in Gaston County. The applicant states that BMA Kings Mountain has experienced 11% growth over the recent three years ending December 31, 2017. BMA Kings Mountain growth warrants placing the stations at this location.

- Relocate more than Three Stations. The applicant states BMA demonstrated a need for no more than 21 stations at BMA Kings Mountain.

In Section E, pages 27-28, the applicant states that its proposal is an effective alternative because of its modest capital expenditure and meeting the growing needs of patients choosing to dialyze at BMA Kings Mountain.

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 1. Bio-Medical Applications of North Carolina, Inc. shall materially comply with all representations made in the certificate of need application.**
- 2. Pursuant to Policy ESRD-2, Bio-Medical Applications of North Carolina, Inc. shall relocate no more than three dialysis stations from FMC Belmont to BMA Kings Mountain for a total of no more than 21 certified stations upon completion of this project, which shall include any home hemodialysis training or isolation stations.**
- 3. Bio-Medical Applications of North Carolina, Inc. shall install plumbing and electrical wiring through the walls for no more than three dialysis stations, which shall include any isolation stations.**
- 4. Upon completion of this project, Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify three dialysis stations at FMC Belmont for a total of no more than 16 dialysis stations at FMC Belmont.**
- 5. Bio-Medical Applications of North Carolina, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**

- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

BMA proposes to relocate three dialysis stations from FMC Belmont to BMA Kings Mountain for a total of 21 dialysis stations at BMA Kings Mountain.

Capital and Working Capital Costs

In Section F.1, page 30, the applicant projects the total capital cost of the project to be \$11,250, with \$2,250 for water treatment equipment and \$9,000 for equipment/furniture.

In Section F, page 33, the applicant provides the assumptions used to project the capital cost.

In Section F, pages 33, 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 31, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	BMA	Total
Accumulated reserves or OE *	\$11,250	\$11,250
Total Financing	\$11,250	\$11,250

* OE = Owner's Equity

Exhibit F-1 contains a letter from the Senior Vice President and Treasurer of Fresenius Medical Care Holdings, Inc., parent company to Bio-Medical Applications of North Carolina, Inc., authorizing the use of accumulated reserves for the capital needs of the project. Exhibit F-2 contains a copy of the Consolidated Balance Sheets from Fresenius Medical Care Holdings, Inc., which showed that as of December 31, 2017 Fresenius Medical Care Holdings, Inc. had \$569,818,000 in cash and equivalents, \$19,822,127,000 in total assets and \$10,542,494,000 in net assets (total assets less total liabilities).

Financial Feasibility

The applicant provided pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Form B, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

BMA Kings Mountain	Operating Year 1 CY2020	Operating Year 2 CY2021
Total Treatments	11,410	12,003
Total Gross Revenues (Charges)	\$45,111,951	47,476,835
Total Net Revenue	\$3,708,649	\$3,890,367
Average Net Revenue per treatment	\$325.03	\$324.11
Total Operating Expenses (Costs)	\$3,547,870	\$3,585,206
Average Operating Expense per treatment	\$310.94	\$298.69
Net Income	\$160,779	\$305,161

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

Conclusion

The Agency reviewed the:

- Application
- 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 availability of sufficient funds for the capital needs of the proposal.
 - The applicant adequately demonstrates 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

BMA proposes to relocate three dialysis stations from FMC Belmont to BMA Kings Mountain for a total of 21 dialysis stations at BMA Kings Mountain.

On page 365, the 2018 SMFP defines the service area for dialysis stations as “a dialysis station’s service area is the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.” Thus, the service area for this facility consists of Gaston County. Facilities may also serve residents of counties not included in their service area.

According to the July 2018 SDR there are five existing and approved dialysis facilities in Gaston County as shown below.

Facility Name	Provider	Location	# of Stations	Percent Utilization
BMA Kings Mountain	FMC	Kings Mountain	18	90.28%
FMC Belmont	FMC	Belmont	19	80.26%
FMC Gastonia	FMC	Gastonia	39	91.67%
FMC South Gaston	FMC	Gastonia	28	79.46%
FMC North Gaston*	FMC	Dallas	12	0.00%

Source: July 2018 SDR, Table B

*Received CON approval but facility is not operational yet.

In Section G.2, page 38, 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 four existing and planned facilities are geographically dispersed across Gaston County, in close proximity to the larger number of ESRD patients residing within Gaston County.”

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

- Although the proposal will not result in an increase in the number of dialysis stations in Gaston County, it involves the transfer of existing stations from one FMC facility in Gaston County to another FMC facility in Gaston County and thus does not duplicate any existing or approved dialysis services in Gaston County.
- The applicant adequately demonstrates that the proposed stations are needed at BMA Kings Mountain.

Conclusion

The Agency reviewed the:

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

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

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

C

In Section H.1, page 40, the applicant provides the current staffing for the facility, and states that BMA Kings Mountain is projected to add seven full time equivalent (FTE) positions as a result of this proposal. The applicant states the facility currently staffs 17.2 FTE positions and will have a staff of 24.12 FTEs upon project completion. In addition, the applicant provides projected direct care staff in Operating Year 2 in Section H.7, page 42.

The assumptions and methodology used to project staffing are provided in Section R. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, Section R. In Exhibits H-1 and H-2, the applicant provides an outline of its continuing education programs. In Section I.3, page 44, the applicant identifies the current medical director for the facility. In Exhibit I-5, the applicant provides a letter from the medical director indicating an interest in continuing to serve as medical director for the proposed services.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section I.1, page 43, the applicant identifies the ancillary and support services necessary for the proposed services.

BMA Kings Mountain – Ancillary and Support Services	
Services	Provider
In-center dialysis/maintenance	BMA on site
Self-care training (in-center)	BMA-on site
Home training HH PD Accessible follow-up program	BMA- on site
Psychological counseling	Gaston County Mental Health-Referral
Isolation – hepatitis	BMA on site
Nutritional counseling	BMA on site
Social Work services	BMA on site
Acute dialysis in an acute care setting	CaroMont-Referral
Emergency care	911, CaroMont
Blood bank services	CaroMont-Referral
Diagnostic and evaluation services	
X-ray services	
Laboratory services	Spectra
Pediatric nephrology	CaroMont-Referral
Vascular surgery	Dr. Randall Bast-Lenoir Dr. Cochupura-Gastonia Dr. Burgess-Charlotte Dr. Hobson, Shelby, Sicilia and Orland-Gastonia
Transplantation services	Carolinas Medical Center-Referral
Vocational rehabilitation & counseling	Gaston, or Cleveland County Vocational Rehabilitation-Referral
Transportation	Gaston Area Transit (PAT); Care First, Med One Medical Transport, Private transport, Jacki McNear

The applicant provides supporting documentation for its ancillary and support services in Exhibits I-2 through I-4.

In Section I, pages 44-45, 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.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

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

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

NA

The applicant is not a 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 make more than minor renovations to 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 handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L.7, page 58, the applicant provides the historical payor mix during CY 2017 at BMA Kings Mountain and FMC Belmont, as shown in the table below.

Payment Sources	BMA Kings Mountain Patients as Percent of Total	FMC Belmont Patients as Percent of Total
Self-Pay/indigent/Charity	1.49%	-0.02%
Medicare	63.89%	69.68%
Medicaid	2.14%	5.37%
Commercial Insurance	7.40%	6.98%
Medicare/Commercial	19.48%	11.25%
Miscellaneous (incl VA)	5.61%	6.74%
Total	100.00%	100.00%

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant's service area.

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance **
2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate
Cleveland	18%	52%	27%	21%	12%	12%
Gaston	16%	52%	28%	16%	12%	12%
Statewide	16%	51%	37%	15%	10%	12%

Source: <http://www.census.gov/quickfacts/table/US/PST045217>; Latest Data 7/1/17 as of 7/17/18

*Excludes "White alone, not Hispanic or Latino"

** "Estimates are not comparable to other geographical levels due to methodology differences that may exist between different data sources. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g. V2017) refers to the final year of the series (2010 thru 2017). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consisting of North Carolina, South Carolina and Georgia, provides an Annual Report which includes aggregate ESRD patient data from all three states. The report does not provide state-specific ESRD patient data, but the aggregate data is likely to be similar to North Carolina's based on the Network's recent annual reports which included state-specific data.

The IPRO SA Network 6 Annual Report (pages 25-26¹) provides the following prevalence data on dialysis patients by age, race, and gender. As of December 31, 2016, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 66% were other than Caucasian and 45% were female.

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 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

¹<https://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/07/NW6-2016-Annual-Report-FINAL.pdf>

and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.3, page 56, the applicant states,

“BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations. The facility will be responsible to provide care to both minorities and handicapped people. The applicant will treat all patients the same regardless of race or handicapped status. In accepting payments from Medicare, Title XVIII of the Social Security Act, and Medicaid, Title XIX, all BMA North Carolina Facilities are obligated to meet federal requirements of the Civil Rights Act, Title VI and the Americans with Disabilities Act.”

In Section L.6, page 57, the applicant states there have been no civil rights complaints lodged against any BMA North Carolina facilities in the past five years.

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.

- (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.1, page 55, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

BMA Kings Mountain Projected Payor Mix Project Year 2, CY 2021				
Payment Source	% Total Patients	% IC Patients	% HHD Patients	% PD Patients
Self-Pay/Indigent/Charity	1.2%	1.49%	3.93%	3.93%
Medicare	63.9%	63.89%	63.51%	63.51%
Medicaid	2.4%	2.14%	0.00%	0.00%
Commercial Insurance	10.8%	7.40%	31.92%	31.92%
Medicare/Commercial	16.9%	19.48%	0.64%	0.64%
Misc. (including VA)	4.8%	5.61%	0.00%	0.00%
Total	100.0%	100.00%	100.00%	100.00%

Note: Totals may not foot due to rounding
 Source: Section L, page 55

As shown in the table above, during the second year of operation, the applicant projects that 1.2% of total services will be provided to self-pay/indigent/charity patients, 81% to Medicare patients (includes Medicare and Medicare/Commercial), and 2.4% to Medicaid patients.

On page 55, 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 for the following reasons:

- The projected payor mix is based on the historical payor mix.
- Projected utilization is reasonable and adequately supported. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L.4, page 57, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section M, page 59, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M-1.

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

BMA proposes to relocate three dialysis stations from FMC Belmont to BMA Kings Mountain for a total of 21 dialysis stations at BMA Kings Mountain.

On page 365, the 2018 SMFP defines the service area for dialysis stations as “*a dialysis station’s service area is the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-*

Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.” Thus, the service area for this facility consists of Gaston County. Facilities may also serve residents of counties not included in their service area.

According to the July 2018 SDR there are four existing and approved dialysis facilities and one proposed facility in Gaston County as shown below.

Facility Name	Provider	Location	# of Stations	Percent Utilization
BMA Kings Mountain	FMC	Kings Mountain	18	90.28%
FMC Belmont	FMC	Belmont	19	80.26%
FMC Gastonia	FMC	Gastonia	39	91.67%
FMC South Gaston	FMC	Gastonia	28	79.46%
FMC North Gaston*	FMC	Dallas	12	0.00%

Source: July 2018 SDR, Table B

*Received CON approval but facility is not operational yet.

In Section N, page 60, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality, and access to the proposed services. On page 60, the applicant states:

“BMA Kings Mountain does not expect this proposal to have effect on the competitive climate in Gaston County. All of the dialysis facilities in Gaston County are operated by Fresenius Medical Care, parent company to BMA Kings Mountain. BMA does not project to see dialysis patients currently being served by another provider in a contiguous county.

This facility has added value stemming from the strength of our relationship with Metrolina Nephrology Associates nephrology practice.....the practice brings together the collaborative efforts of 34 very qualified nephrologists to provide care for the patients choosing to dialyze at BMA Kings Mountain.

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

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

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

- The cost-effectiveness of the proposal (see Sections F and R of the application and any exhibits)
- Quality services will be provided (see Section O of the application and any exhibits)

- Access will be provided to underserved groups (see Section L of the application and any exhibits)

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.

- (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 Exhibit A-4, 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 a total of 114 of this type of facility located in North Carolina.

In Section O, page 64, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care occurred in any of these facilities. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all 114 facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The application is conforming with all applicable Criteria and Standards for End-Stage Renal Disease Services. The specific criteria are discussed below.

SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES

10A NCAC 14C .2203 PERFORMANCE STANDARDS

(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.

-NA- The applicant is not proposing to establish a new End Stage Renal Disease facility.

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

-C- In Section C, page 15, the applicant projects that BMA Kings Mountain will serve 68 in-center patients on 21 stations, or a rate of 3.2 patients per station per week, as of the end of the first operating year following project completion. 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 13-16, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.