

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: January 22, 2021

Findings Date: January 22, 2021

Project Analyst: Kim Meymandi

Team Leader: Fatimah Wilson

Project ID #: F-11983-20

Facility: BMA Kings Mountain

FID #: 150476

County: Gaston

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

Project: Add no more than one dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 22 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.

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Bio-Medical Applications of North Carolina, Inc. (hereinafter referred to as “the applicant” or BMA) proposes to add no more than one dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 22 stations upon project completion. Bio-Medical Applications of North Carolina, Inc. is a wholly owned subsidiary of Fresenius Medical Care Holdings, Inc. (FMC or Fresenius).

Need Determination (Condition 2)

Chapter 9 of the 2020 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table 9D, page 170, the county need methodology shows there is not a county need determination for additional dialysis stations in Gaston County.

However, the applicant is eligible to apply for additional dialysis stations in an existing facility pursuant to Condition 2 of the facility need methodology in the 2020 SMFP, if the utilization rate for the facility as reported in the 2020 SMFP is at least 75 percent or 3.0 patients per station per week, as stated in Condition 2.a. The utilization rate reported for BMA Kings Mountain is 91.67 percent or 3.67 patients per station per week, based on 66 in-center dialysis patients and 18 certified dialysis stations (66 patients / 18 stations = 3.67; $3.67 / 4 = 91.67\%$).

As shown in Table 9E, page 171 of the 2020 SMFP, based on the facility need methodology for dialysis stations, the potential number of stations needed is up to three additional stations; thus, the applicant is eligible to apply to add up to three stations during the 2020 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than one new station to the facility, which is consistent with the 2020 SMFP calculated facility need determination for up to three stations; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

Policies

There is one policy in the 2020 SMFP that is applicable to this review, Policy GEN-3: *Basic Principles*.

Policy GEN-3, pages 30-31 of the 2020 SMFP, states:

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

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section B.5, pages 14-16; Section N, pages 55-57, Section O, pages 58-61; and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section B.5(b), pages 15-16; Section L, pages 48-51; Section N, pages 55-57, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value – The applicant describes how it believes the proposed project would maximize healthcare value in Section B.5(c), page 16; Sections F and K, and Section N, pages 55-57. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

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

Conclusion

The Agency reviewed the:

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

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

- The applicant adequately demonstrates that the application is consistent with Condition 2 of the facility need methodology as applied from the 2020 SMFP.
- The applicant adequately demonstrates that the application is consistent with Policy GEN-3 because the applicant adequately demonstrates how BMA Kings Mountain’s projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need.

- (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.

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The applicant proposes to add no more than one dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 22 stations upon project completion.

BMA Kings Mountain provides in-center (IC) dialysis as well as both a peritoneal dialysis (PD) and a home hemodialysis (HH) program.

The following table, summarized from page 7 of the application, shows the current and projected number of dialysis stations at BMA Kings Mountain:

BMA Kings Mountain

# OF STATIONS	DESCRIPTION	PROJECT ID #
21	Total # of existing certified stations as reported in the SMFP in effect on the day the review will begin	
1	# of stations to be added as part of this project	
0	# of stations to be deleted as part of this project	
0	# of stations previously approved to be added but not yet certified	
0	# of stations previously approved to be deleted but not yet certified	
0	# of stations proposed to be added in an application still under review	
0	# of stations proposed to be deleted in an application still under review	
22	Total # of stations upon completion of all facility projects	

As illustrated in the table above, in this application, the applicant proposes to add one dialysis station for a total of 22 stations upon project completion.

Patient Origin

On page 113, the 2020 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancey counties.*” 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.2, page 19, the applicant provides the patient origin for in-center (IC), home hemodialysis (HH), and peritoneal dialysis (PD) patients at BMA Kings Mountain for the last full operating year (CY2019), as summarized in the table below.

BMA Kings Mountain Patient Origin - CY2019

COUNTY	# IC PATIENTS	% IC Total	# HH Patients	% HH Total	# PD Patients	% PD Total
Gaston	25	42.4%	3	42.9%	2	25.0%
Cleveland	31	52.5%	1	14.3%	4	50.0%
Lincoln	3	5.1%	1	14.3%	0	0.0%
Mecklenburg	0	0.0%	1	14.3%	1	12.5%
Rutherford	0	0.0%	0	0.0%	1	12.5%
South Carolina	0	0.0%	1	14.3%	0	0.0%
Total	59	100.0%	7	0.0%	8	100.0%

Totals may not sum due to rounding

The applicant states that the projected IC, HH, and PD patient origin is based upon the facility census as of June 30, 2020 and provides the following table from page 20.

BMA Kings Mountain Patient Origin – June 30, 2020

COUNTY	# IC PATIENTS	# HH Patients	# PD Patients
Gaston	26.0	2.0	1.0
Cleveland	29.0	5.0	4.0
Lincoln	3.0	1.0	0.0
Mecklenburg	0.0	1.0	0.0
Rutherford	1.0	0.0	0.0
South Carolina	0.0	1.0	0.0
Total	59.0	10.0	5.0

The following table summarizes projected patient origin for the second full operating year (CY2023) following project completion, as provided in Section C.3, page 20.

BMA Kings Mountain Projected Patient Origin - CY2023

COUNTY	# IC PATIENTS	% IC Total	# HH Patients	% HH Total	# PD Patients	% PD Total
Gaston	30.6	46.9%	2.4	22.1%	1.2	21.8%
Cleveland	30.7	46.9%	5.3	49.7%	4.2	78.2%
Lincoln	3.0	4.6%	1.0	9.4%	0.0	0.0%
Mecklenburg	0.0	0.0%	1.0	9.4%	0.0	0.0%
Rutherford	1.0	1.5%	0.0	0.0%	0.0	0.0%
South Carolina	0.0	0.0%	1.0	9.4%	0.0	0.0%
Total	65.3	100.0%	10.7	100.0%	5.4	100.0%

Totals may not sum due to rounding

In Section C, pages 20-24, the applicant provides the assumptions and methodology it used to project IC, HH, and PD patient origin. The applicant’s assumptions are reasonable and adequately supported, based on the following:

- The applicant projects patient origin at BMA Kings Mountain based on its existing population.
- The applicant increases the number of projected future patients based on the Five Year Average Annual Change Rates of Gaston and Cleveland Counties.

Analysis of Need

In Section C.3, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services.

On page 25 the applicant explains the typical three day per week schedule for in-center patients to receive dialysis and states the failure to receive dialysis services will lead to patient death. The applicant states:

“The NC SMFP recognizes that this patient population requires frequent and regular treatment. ... The need that this population has for the proposed services is a function of the

individual patient need for dialysis care and treatment. ... BMA has identified the population to be served as 63.4 in-center dialysis patients, and 15.8 home dialysis patients, projected to be dialyzing with the facility as of the end of the first Operating Year of the project. The in-center utilization rate is calculated to be 2.88 patients per station, or 72.1% utilization.”

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

- According to the 2020 SMFP, as of December 31, 2018, BMA Kings Mountain was operating at a rate of 3.67 patients per station per week, or 91.67 percent of capacity.
- The applicant demonstrates eligibility to add dialysis stations to its facility under Condition 2 of the facility need methodology. The discussion regarding the facility need methodology found in Criterion (1) is incorporated herein by reference.
- The applicant projects a utilization rate of 2.9 in-center patients per station per week dialyzing at BMA Kings Mountain as of the end of the first 12 months of operation following certification of the additional station which exceeds the performance standards 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 additional stations as set forth in the Performance Standards in Rule 10A NCAC 14C .2203

Projected Utilization

In-Center Projected Utilization

In Section C.3, page 21 and in Form C Utilization subsection of Section Q, the applicant provides the methodology used to project the IC utilization for OY1 and OY2, as summarized in the table below.

BMA KINGS MOUNTAIN IN-CENTER PATIENTS

	Gaston County	Cleveland County
The applicant begins with facility census of Gaston County and Cleveland County patients as of June 30, 2020.	26	29
The applicant projects the patient population forward six months to December 31, 2020, using one half the county Five-year AACR which is 4.8% for Gaston County and 0.8% for Cleveland County.	$26 \times 1.024 = 26.6$	$29 \times 1.008 = 29.2$
The applicant projects the patient population forward one year to December 31, 2021, using the county five-year AACR.	$26.6 \times 1.048 = 27.9$	$29.2 \times 1.016 = 29.7$
The applicant sums the Gaston and Cleveland County patients and adds four patients residing in counties other than Gaston and Cleveland. This is the starting census for the project.	$27.9 + 29.7 + 4 = 61.6$	
The applicant projects the Gaston and Cleveland County patients forward one year to December 31, 2022, using the county five-year AACR.	$27.9 \times 1.048 = 29.2$	$29.7 \times 1.016 = 30.2$
The applicant sums the Gaston and Cleveland County patients and adds four patients residing in counties other than Gaston and Cleveland. This is the projected ending census for Operating Year (OY1).	$29.2 + 30.2 + 4 = 63.4$	
The applicant projects the Gaston and Cleveland County patients forward one year to December 31, 2023, using the county five-year AACR.	$29.2 \times 1.048 = 30.6$	$30.2 \times 1.016 = 30.7$
The applicant sums the Gaston and Cleveland County patients and adds four patients residing in counties other than Gaston and Cleveland. This is projected ending census for Operating Year (OY2).	$30.6 + 30.7 + 4 = 65.3$	

In both Section C, pages 19-21, and Section Q, pages 70-72, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- Operating Year 1 is January 1, 2022 to December 31, 2022 (CY2022).
- Operating Year 2 is January 1, 2023 to December 31, 2023 (CY2023).
- The applicant begins its utilization projections by using the BMA Kings Mountain patient census as of June 30, 2020 which was 59 total IC patients: 26 Gaston County patients, 29 Cleveland County patients, 3 Lincoln County patients and 1 Rutherford County patient.
- The applicant projects the Gaston County and Cleveland County patient census at BMA Kings Mountain will increase by the Gaston County and Cleveland County Five Year AACR of 4.8% and 1.6% respectively as published in the 2020 SMFP.
- The applicant does not project any growth of the Lincoln and Rutherford County patients and will carry those patients forward into projections of future patient census.

Therefore, at the end of OY1 (CY2022) BMA Kings Mountain is projected to serve 63.4 in-center patients on 22 stations; and at the end of OY2 (CY2023) the facility is projected to serve 65.3 in-center patients on 22 stations.

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

- OY1: 2.9 patients per station per week, or 72.5% utilization [$63.4 / 22 \text{ stations} = 2.9 / 4 = 0.725$ or 72.5%]
- OY 2: 2.9 patients per station per week, or 75.0% utilization [$65.3 / 22 \text{ stations} = 3.0 / 4 = 0.750$ or 75.0%].

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

- The applicant projects future utilization based on the most recent historical patient census.
- The applicant utilized a projected annual growth rate of 4.8 percent for Gaston County patients and 1.6 percent for Cleveland County which reflects the Gaston and Cleveland County Five-Year AACR as published in Table 9C of the 2020 SMFP.
- The applicant assumes the patients residing outside of Gaston and Cleveland Counties will continue to dialyze at BMA Kings Mountain and are added to the projections without any future growth through the first two operating years of the project.
- The projected utilization rate by the end of OY1 exceeds the minimum standard of 2.8 patients per station per week as required by 10A NCAC 14C .2203.

Peritoneal and Home Hemodialysis Patients

In both Section C, pages 22-24, and Section Q, pages 73-75, the applicant provides the assumptions and methodology used to project PD and HH utilization, which is summarized below.

- Operating Year 1 is January 1, 2022 to December 31, 2022 (CY2022).
- Operating Year 2 is January 1, 2023 to December 31, 2023 (CY2023).
- The applicant begins its utilization projections by using the BMA Kings Mountain PD and HH patient census as of June 30, 2020 which was:
 - Five total PD patients: Four Cleveland County patients and one patient from Gaston County; and
 - 10 total HH patients: Two from Gaston County, five from Cleveland County and one patient each from Lincoln County, Mecklenburg County and South Carolina.
 - The PD and HH patients not residing in Gaston and Cleveland Counties will be carried forward into projections of future patient census however, the applicant does not project any growth of the PD and HH patients living outside of Gaston and Cleveland Counties.
- The applicant utilized a projected annual growth rate of 4.8 percent for Gaston County patients and 1.6 percent for Cleveland County which reflects the Five-Year AACR as published in Table 9C pages 166 and 167 of the 2020 SMFP for Gaston and Cleveland Counties.

BMA KINGS MOUNTAIN HOME HEMODIALYSIS PATIENTS

	Gaston	Cleveland
The applicant begins with the Gaston County and Cleveland County patient population as of June 30, 2020.	2	5
The applicant projects the patient population forward six months to December 31, 2020, using one half the county Five-year AACR which is 4.8% for Gaston County and 0.8% for Cleveland County.	$2 \times 1.024 = 2.05$	$5 \times 1.008 = 5.04$
The applicant projects the patient population forward one year to December 31, 2021, using the county five-year AACR.	$2.05 \times 1.048 = 2.15$	$5.04 \times 1.016 = 5.12$
The applicant sums the Gaston and Cleveland County patients and adds three patients residing in counties other than Gaston and Cleveland. This is the starting census for the project.	$2.15 + 5.12 + 3 = 10.27$	
The applicant projects the Gaston and Cleveland County patients forward one year to December 31, 2022, using the county five-year AACR.	$2.15 \times 1.048 = 2.25$	$5.12 \times 1.016 = 5.20$
The applicant sums the Gaston and Cleveland County patients and adds three patients residing in counties other than Gaston and Cleveland. This is the projected ending census for Operating Year (OY1).	$2.25 + 5.20 + 3 = 10.5$	
The applicant projects the Gaston and Cleveland County patients forward one year to December 31, 2023, using the county five-year AACR.	$2.25 \times 1.048 = 2.36$	$5.20 \times 1.016 = 5.28$
The applicant sums the Gaston and Cleveland County patients and adds three patients residing in counties other than Gaston and Cleveland. This is projected ending census for Operating Year (OY2).	$2.36 + 5.28 + 3 = 10.6$	

Note: Some of the calculations above are incorrect, however, they are minor and do not change the overall outcome

BMA KINGS MOUNTAIN HOME PERITONEAL DIALYSIS PATIENTS

	Gaston	Cleveland
The applicant begins with the Gaston County and Cleveland County patient population as of June 30, 2020.	1	4
The applicant projects the patient population forward six months to December 31, 2020, using one half the county Five-year AACR which is 4.8% for Gaston County and 1.6% for Cleveland County.	$1 \times 1.024 = 1.02$	$4 \times 1.008 = 4.03$
The applicant projects the patient population forward one year to December 31, 2021, using the county five-year AACR.	$1.02 \times 1.048 = 1.07$	$4.03 \times 1.016 = 4.10$
The applicant sums the Gaston and Cleveland County patients. This is the starting census for the project.	$1.07 + 4.10 = 5.17$	
The applicant projects the Gaston and Cleveland County patients forward one year to December 31, 2022, using the county five-year AACR.	$1.07 \times 1.048 = 1.12$	$4.10 \times 1.016 = 4.17$
The applicant sums the Gaston and Cleveland County patients. This is the projected ending census for Operating Year (OY1).	$1.12 + 4.17 = 5.29$	
The applicant projects the Gaston and Cleveland County patients forward one year to December 31, 2023, using the county five-year AACR.	$1.12 \times 1.048 = 1.18$	$4.16 \times 1.016 = 4.23$
The applicant sums the Gaston and Cleveland County patients. This is projected ending census for Operating Year (OY2).	$1.18 + 4.23 = 5.41$	

Note: Some of the calculations above are incorrect, however, they are minor and do not change the overall outcome

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

- The applicant projects future utilization based on the most recent historical patient census.
- The applicant utilized a projected annual growth rate of 4.8 percent for Gaston County patients and 1.6 percent for Cleveland County which reflects the Five-Year AACR as published in Table 9C of the 2020 SMFP for each county.
- The applicant conservatively does not project growth for the patients living outside Gaston and Cleveland Counties.

Access to Medically Underserved Groups

In Section C.7, pages 25-26, the applicant states,

“Fresenius 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, ability to pay 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.”

On page 27, the applicant provides the following estimated percentages of dialysis patients for each medically underserved group during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

**BMA Kings Mountain
Estimated Percentage of Patients by Group CY 2023**

Medically Underserved Groups	Percentage of Total Patients
Low income persons	31.1%
Racial and ethnic minorities	59.5%
Women	40.5%
Handicapped persons	13.5%
The elderly	40.5%
Medicare beneficiaries	87.8%
Medicaid recipients	25.7%

Single patients may be counted in multiple categories

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.

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 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, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose to reduce a service, eliminate a service, or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

The applicant proposes to add no more than one dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 22 stations upon project completion.

In Section E, page 32, 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 maintaining the status quo is not an effective alternative due to the growth rate at the facility.
- *Applying for more than one station* - The applicant states that this alternative is not acceptable because currently, they do not project a need to add more than one station at BMA Kings Mountain.

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

- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

1. **Bio-Medical Applications of North Carolina, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
 2. **Pursuant to Condition 2 of the facility need determination in the 2020 SMFP, the certificate holder shall develop no more than one additional in-center dialysis station for a total of no more than 22 in-center dialysis stations at BMA Kings Mountain.**
 3. **Progress Reports:**
 - a. **Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. **The certificate holder shall complete all sections of the Progress Report form.**
 - c. **The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. **Progress reports shall be due on the first day of every sixth month. The first progress report shall be due on August 1, 2021. The second progress report shall be due on November 1, 2021 and so forth.**
 4. **The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to add no more than 1 dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 22 stations upon project completion.

Capital and Working Capital Costs

In Section Q, Form F.1a, the applicant projects the total capital cost of the project, as shown in the table below.

BMA Kings Mountain Capital Costs	
Non-Medical Equipment	\$750
Furniture	\$3,000
Total	\$3,750

In Section Q, page 78, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant has considerable knowledge and experience regarding the costs involved with adding a ESRD station.
- The applicant has a history of purchasing similar items for necessary for ESRD station expansion.

In Section F, pages 34-35, the applicant states that there will be no start-up or initial operating expenses associated with the proposed project because BMA Kings Mountain is an existing facility that is already operational.

Availability of Funds

In Section F, page 33, 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.	Total
Loans	\$0	\$ 0
Accumulated reserves or OE *	\$3,750	\$3,750
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$3,750	\$3,750

* OE = Owner's Equity

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the following:

- Exhibit F-2 contains a letter, dated October 15, 2020, from the Senior Vice President and Treasurer for 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.
- The applicant documents that it has adequate cash and assets to fund the capital cost of the proposed project.

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 F.2, page 80, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

Projected Revenues and Operating Expenses		
BMA Kings Mountain	Operating Year 1 CY 2022	Operating Year 2 CY 2023
Total Treatments	11,558.3	11,877.6
Total Gross Revenues (Charges)	72,713,171	74,721,793
Total Net Revenue	3,443,581	3,536,869
Average Net Revenue per Treatment	297.93	297.78
Total Operating Expenses (Costs)	3,407,691	3,477,348
Average Operating Expenses per Treatment	\$295	\$293
Net Income	35,890	59,521

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

- The applicant bases charges and expenses on historical revenue and expenses for BMA's North Carolina facilities.
- 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 based on the following:

- 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 for the reasons stated above.
- 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 revenues and operating expenses for the reasons stated above.

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

C

The applicant proposes to add no more than one dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 22 stations upon project completion.

On page 113, the 2020 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” BMA Kings Mountain is located in Gaston County. 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 Table 9B of the 2020 SMFP, there are five existing or approved dialysis facilities in Gaston County, all of which are owned and operated by BMA. Information on these dialysis facilities, from Table 9B of the 2020 SMFP, is provided in the table below:

**BMA Kings Mountain Dialysis Facilities
 Certified Stations and Utilization as of December 31, 2018**

Dialysis Facility	Owner	Certified Stations	# of IC Patients	Percent Utilization	Patients Per Station
BMA Kings Mountain	BMA	18	66	91.67%	3.6667
Fresenius Kidney Care North Gaston	BMA	0	0	0	0
Fresenius Medical Care Belmont	BMA	19	72	94.74%	3.7895
Fresenius Medical Care Gastonia	BMA	39	155	99.36%	3.9744
Fresenius Medical Care South Gaston	BMA	28	86	76.79%	3.0714
Total		104	379		

Source: 2020 SMFP, Table 9B

In Section G.2, page 38, the applicant explains why it believes the proposal would not result in the unnecessary duplication of existing or approved dialysis services in Gaston County. The applicant states it is not projecting to serve patients currently served in another facility but rather the stations are needed to serve the projected patient census at BMA Kings Mountain. Projected utilization starts with the current patient population of the facility and grows that patient census.

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

- There is a facility need determination in the 2020 SMFP at BMA Kings Mountain for more than the proposed one dialysis station. The applicant proposes to add one station.

- The applicant adequately demonstrates that the proposed dialysis stations are needed in addition to the existing or approved dialysis stations.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- 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.

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

C

The applicant proposes to add no more than one dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 22 stations upon project completion.

In Section Q Form H Staffing, the applicant provides a table showing current and projected staffing in full time equivalent (FTE) positions for BMA Kings Mountain, as illustrated in the following table.

Position	Current FTE Staff	Projected FTE Staff	Projected FTE Staff
	As of 8/2020	OY1 (1/1/2022 to 12/31/2022)	OY2 (1/1/2023 to 12/31/2023)
Administrator	1.00	1.00	1.00
RNs	3.00	3.50	3.50
Home Training Nurse	1.00	1.00	1.00
Technicians (PCT)	7.00	8.00	8.00
Dietician	0.50	0.67	0.67
Social Worker	0.50	0.67	0.67
Maintenance	0.50	0.50	0.50
Admin/Business Office	1.00	1.00	1.00
Other: FMC Dir. Operations	0.15	0.15	0.15
Other: In-Service	0.15	0.15	0.15
Other: Chief Tech	0.15	0.15	0.15
TOTAL	14.95	16.79	16.79

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 Operating Costs. In Section H, page 39, the applicant describes the methods used to recruit or fill new positions and its existing training and

continuing education programs. In Section H, page 41, the applicant identifies the current medical director. In Exhibit H-4, 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 based on the following:

- The applicant projects an increase in the FTE staffing positions necessary to accommodate the proposed increase in healthcare services at BMA Kings Mountain.
- The increased costs are accounted for in the budgeted Operating Costs
- The methods used to recruit or fill new positions and the existing training and continuing education programs are provided.
- A letter from the current medical director indicating an interest in continuing to serve as medical director for the proposed services is provided.

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 described above.

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

C

The applicant proposes to add no more than one dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 22 stations upon project completion.

Ancillary and Support Services

In Section I, page 42 the applicant identifies the necessary ancillary and support services for the proposed services and explains how each ancillary and support service is or will be made available.

ANCILLARY AND SUPPORT SERVICES	
SERVICES	PROVIDER
Self-care training	Provided on site by the facility
Home training HH PD Accessible follow-up program	
Isolation for hepatitis B positive patients	
Nutritional counseling	
Social Work services	
Laboratory services	
Vascular Surgery	Dr. Randall Bast, Lenoir, NC; Dr. Orland, Sicilia, Dr. Kochupura, Gastonia; Dr. Burgess, Dr. Lesni, Charlotte
Pediatric Nephrology	Referral to Atrium Health-CMC
Acute dialysis in an acute care setting	Caromont Regional Hospital
Transplantation services	Wake Forest Baptist Hospital; Duke UMC; UNC Hospital, Emory
Emergency care	Provided by facility staff until ambulance arrival
Blood bank services	Caromont Regional Hospital
X-ray, diagnostic and evaluation services	Caromont Regional Hospital
Psychological counseling	Referral to A Caring Alternative
Vocational rehabilitation & counseling	Referral to Burke Vocational
Transportation	Greenway Transportation; Specialized Transportation

The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant identifies the necessary ancillary and support services for dialysis patients located in or near Gaston County and how these will be made available.
- The applicant describes how the necessary ancillary and support services will be coordinated with the existing health care system.

Coordination

In Section I, page 43 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 has numerous years of experience serving the needs of dialysis patients.
- The applicant has established relationships and agreements with the community health care and ancillary service providers and where dialysis patients can receive appropriate referrals for necessary services and care related to their condition.

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.

- (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

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

other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

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

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and ... persons [with disabilities], which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L, page 51, the applicant provides the historical payor mix for BMA Kings Mountain during the last full operating year (CY2019) for its existing services, as shown in the table below.

**BMA Kings Mountain
 Historical Payor Mix CY 2019**

Payor Category	In-Center		HOME HEMODIALYSIS		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	0.41	0.69%	0.00	0.00%	0.00	0.00%
Insurance*	2.77	4.69%	0.25	3.64%	2.21	27.62%
Medicare*	37.85	64.15%	4.29	61.25%	5.76	72.01%
Medicaid*	2.06	3.49%	0.00	0.00%	0.00	0.00%
Medicare/Commercial	12.49	21.17%	2.46	35.12%	0.03	0.36%
Miscellaneous (Incl. VA)	3.42	5.80%	0.00	0.00%	0.00	0.00%
Total	59.00	100.00%	7.00	100.00%	8.00	100.00%

Totals may not sum due to rounding

*Including any managed care plans

In Section L, page 50, the applicant provides the following comparison.

	Percentage of Total Patients Served by the Facility or Campus during the Last Full OY	Percentage of the Population of the Service Area*	
		Gaston County	Cleveland County
Female	40.5%	51.7%	51.9%
Male	59.5%	48.3%	48.1%
Unknown	0.0%	0.0%	0.0%
64 and Younger	59.5%	83.7%	81.0%
65 and Older	40.5%	16.3%	19.0%
American Indian	1.4%	0.6%	0.4%
Asian	1.4%	1.6%	1.1%
Black or African-American	52.7%	17.9%	20.8%
Native Hawaiian or Pacific Islander	0.0%	0.1%	Z
White or Caucasian	41.9%	71.1%	72.8%
Other Race	2.7%	8.7%	4.9%
Declined / Unavailable	0.0%		

*The percentages can be found online using the United States Census Bureau's QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>. Just enter in the name of the county.

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, the applicant states in Section L, page 51, that the facility is not under any obligation to provide uncompensated care, community service, or access by minorities and handicapped persons.

In Section L, page 52, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L.3, page 52, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as summarized in the following table.

**BMA Kings Mountain
 Projected Payor Mix CY2023**

Payment Source	In-Center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	0.5	0.69%	0.00	0.00%	0.00	0.00%
Insurance*	3.1	4.69%	0.39	3.64%	1.49	27.62%
Medicare*	41.9	64.15%	6.52	61.25%	3.89	72.01%
Medicaid*	2.3	3.49%	0.00	0.00%	0.00	0.00%
Medicare/Commercial	13.8	21.17%	3.74	35.12%	0.02	0.36%
Miscellaneous (incl. VA)	3.8	5.80%	0.00	0.00%	0.00	0.00%
Total	65.3	100.00%	10.64	100.00%	5.41	100.00%

Totals may not sum due to rounding

*Including any managed care plans

As shown in the table above, in the second full year of operation, the applicant projects that 0.69% of in-center dialysis services will be provided to self-pay patients, 85.32% to Medicare patients (including Medicare/Commercial), and 3.49% to Medicaid patients. In addition, 96.37% and 0.00% of HH services will be provided to Medicare (including Medicare/Commercial) and Medicaid patients, respectively, and 72.37% and 0.00% of PD services will be provided to Medicare (including Medicare/Commercial) and Medicaid patients respectively.

On page 52, the applicant provides the assumptions and methodology it uses to project payor mix during the second full year of operation following completion of the project, stating the payor mix is based upon recent facility history of actual treatment volumes.

The projected payor mix is reasonable and adequately supported because the projected payor mix is based on the historical payor mix and treatment volumes of BMA Kings Mountain.

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.5., page 53, 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 54, 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-2. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following:

- The applicant offers the facility as a clinical learning site for students from Gaston College.
- The applicant provides a copy of the letter sent to Gaston College offering training opportunities in Exhibit M-2.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.

- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to add no more than one dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 22 stations upon project completion.

On page 113, the 2020 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” BMA Kings Mountain is located in Gaston County. 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 Table 9B of the 2020 SMFP, there are five existing or approved dialysis facilities in Gaston County, all of which are owned and operated by BMA. Information on these dialysis facilities, from Table 9B of the 2020 SMFP, is provided in the table below:

**BMA Kings Mountain Dialysis Facilities
 Certified Stations and Utilization as of December 31, 2018**

Dialysis Facility	Owner	Certified Stations	# of IC Patients	Percent Utilization	Patients Per Station
BMA Kings Mountain	BMA	18	66	91.67%	3.6667
Fresenius Kidney Care North Gaston	BMA	0	0	0	0
Fresenius Medical Care Belmont	BMA	19	72	94.74%	3.7895
Fresenius Medical Care Gastonia	BMA	39	155	99.36%	3.9744
Fresenius Medical Care South Gaston	BMA	28	86	76.79%	3.0714
Total		104	379		

Source: 2020 SMFP, Table 9B

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 55, 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 56, the applicant states:

“Approval of this application will allow the BMA Kings Mountain to continue serving patients who reside in the area. Consequently, 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 56, the applicant states:

“Quality of care is not negotiable. ... 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 56, 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 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 adequately 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 (*if applicable*).
- 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 A Facilities, 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 the applicant or a related entity located in North Carolina.

In Section O.2, page 61, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care that resulted in a finding of “*Immediate Jeopardy*” 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 Fresenius related 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. 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- BMA Kings Mountain is an existing facility. Therefore, this Rule is not applicable to this review.

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

(1) an existing dialysis facility; or

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

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

-C- In Section C, pages 20-21, and Form C in Section Q, the applicant projects that BMA Kings Mountain will serve 63.4 in-center patients on 22 stations, or a rate of 2.9 patients per station per week or 72.5% ($63.4 / 22 = 2.9/4 = 0.725$ or 72.5%), as of the end of the first operating year (CY2022) following project completion. This exceeds the

minimum performance standard requirement of 2.8 patients per station per week. 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 20-21, in Section Q, Form C, pages 70-72, the applicant provides the assumptions and methodology it used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.