

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: June 13, 2022

Findings Date: June 13, 2022

Project Analyst: Donna Donihi

Co-Signer: Gloria C. Hale

Project ID #: F-012203-22

Facility: Fresenius Kidney Care North Gaston

FID #: 160496

County: Gaston

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

Project: Add no more than four dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 16 dialysis stations upon project completion.

REVIEW CRITERIA

G.S. 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. (hereinafter referred to as “the applicant or BMA”) proposes to add four dialysis stations to Fresenius Kidney Care North Gaston, pursuant to Condition 1 of the facility need methodology, for a total of 16 stations upon completion.

In Section A, page 12 -13, the applicant states its parent company is Bio-Medical Applications of North Carolina, Inc. (*BMA*) is a wholly owned subsidiary of Fresenius Medical Care Holdings, Inc. The applicant uses Bio-Medical Application of North Carolina, Inc. (Bio-Medical) interchangeably with BMA to refer to itself or its facilities. References to Bio-Medical should be interpreted to mean BMA unless otherwise specified. The applicant uses Fresenius Medical Care Holdings (Fresenius) interchangeably with FMCH to refer to itself or its facility. References to (FMCH) should be interpreted to mean Fresenius Medical Care Holdings unless otherwise specified.

Need Determination

Chapter 9 of the 2022 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 9C, page 139, 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 1 of the facility need methodology in the 2022 SMFP if the facility is a “new,” “small,” or “new and small” facility as defined in the 2022 SMFP, and if the facility’s current reported utilization is at least 75 percent, or 3.0 patients per station in a given week. “Current” means in-center utilization as of a reporting date no more than 90 days before the date the certificate of need application is submitted. If applying pursuant to Condition 1, the facility may only apply once during the calendar year.

In Section B, page 19, the applicant reports the following:

Facility Need Methodology Condition 1 (New and Small Facilities Only)	Response
Number of months the facility had been certified as of the data cut-off date in the SMFP	12
Number of stations in the facility as of the data cut-off date in the SMFP	12
According to Table 9A in the 2022 SMFP, the facility is designated as new, small, or new and small	Small
Number of stations proposed in this application	4
Number of in-center patients per station as of the current reporting date	3.67
Current Reporting Date (no more than 90 days before the application is submitted)	12/31/2021
Previous Reporting Date (six months prior to the Current Reporting Date)	6/30/2021

Application of the facility need methodology for Condition 1 indicates that up to a potential maximum of five additional stations are needed at this facility, as illustrated in the following table.

1	# of In-center Patients as of the Current Reporting Date	44.0
2	# of In-Center Patients as of the Previous Reporting Date	32.0
3	Subtract Line 2 from Line 1 (Net In-center Change for 6 Months)	12.0
4	Divide Line 3 by Line 2 (6-month Growth Rate)	.375
5	Multiply Line 4 by 2 (Annual Growth Rate)	.750
6	Multiply Line 5 by Line 1 (New Patients)	33.0
7	Add Line 6 to Line 1 (Total Patients)	77.0
8	Divide Line 7 by 2.8 (Total # of Stations Needed)	27.5
9	# of Stations as of the Application Deadline [^]	12.0
10	Subtract Line 9 from Line 8 (Additional Stations Needed)	16.0

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is 16, based on rounding allowed in Condition 1.b.(vii). Condition 1.c of the facility need methodology states, “*The facility may apply for any number of stations up to the number calculated in Condition 1.b.vii, up to a maximum of 10 stations.*” The applicant proposes to add 4 new stations; therefore, the application is consistent with Condition 1 of the facility need determination for dialysis stations.

Policies

There is one policy in the 2022 SMFP which is applicable to this review. *Policy GEN-3: Basic Principles*, on page 30 of the 2022 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, pages 21-22; Section N, page 78; Section O, pages 80-82, and referenced exhibits. The information provided by the applicant is reasonable and 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, page 22-23; Section L, pages 69-75; Sections N, page 77-78, and referenced exhibits. The information provided by the applicant is reasonable and 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, pages 22-23; Section N, page 77-78; Section Q; and referenced exhibits. The information provided by the applicant regarding its efforts to maximize healthcare value is reasonable and supports the determination that the applicant’s proposal would maximize healthcare value.

Conclusion

The Agency reviewed the:

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

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

- The applicant adequately demonstrates that the application is consistent with the facility need methodology as applied from the 2022 SMFP.
- The applicant adequately demonstrates that the application is consistent with Policy GEN -3 based on how it describes the facility’s policies and programs, which promote the concepts of quality, equitable access and maximum value for resources.

(2) Repealed effective July 1, 1987.

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

C

The applicant proposes to add four dialysis stations to Fresenius Kidney Care North Gaston pursuant to condition 1 of the facility need methodology for a total of 16 stations upon project completion.

In Section A.5 Page 15, the applicant provides the following table.

# OF STATIONS	DESCRIPTION	PROJECT ID #
12	Total # of existing certified stations as reported in the SMFP in effect on the day the review will begin	
4	# of stations to be added as part of this project	F-12203-22
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	
16	Total # of stations upon completion of all facility projects	

As illustrated in the table above, the applicant proposes to add four dialysis stations for a total of 16 stations upon project completion.

Patient Origin

On page 115, the 2022 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.” Thus, the service area for this facility consists of Gaston County. Facilities may serve residents of counties not included in their service area.

In Sections C.2 and C.3, pages 25- 28, the applicant provides the in-center (IC) patient origin Home Dialysis and Peritoneal Dialysis Patients for Fresenius Kidney Care North Gaston during the last full operating year, January 1, 2021 – December 31, 2021 (CY 2021), and the projected patient origin for the second full operating year following project completion, January 1, 2024 - December 31, 2024 (CY 2024), as summarized in the following tables. The facility does serve home training patients and does propose to continue to provide those services as part of this project.

Fresenius Kidney Care North Gaston Patient Origin						
01/01/2021 to 12/31/2021						
	In-Center		Home Hemodialysis		Peritoneal Dialysis	
County	Patients	% of Total	Patients	% of Total	Patients	% of total
Gaston	40.0	90.91%	23.0	53.49%	14.0	63.64%
Avery			1.0	2.33%		
Cleveland	2.0	4.55%	8.0	18.60%	5.0	22.73%
Lincoln	2.0	4.55%	4.0	9.30%	2.0	9.09%
Mecklenburg			1.0	2.33%		
Rutherford			1.0	2.33%		
South Carolina			5.0	11.63%	1.0	4.55%
Total	44.0	100.00%	43.00	100.00%	22.0	100.00%

Source: Section C, pages 25-29

Projected Patient Origin						
01/01/2024 to 12/31/2024						
	In-Center		Home Hemodialysis		Peritoneal Dialysis	
County	Patients	% of Total	Patients	% of Total	Patients	% of total
Gaston	43.7	91.6%	25.1	56.00%	15.3	65.70%
Avery			1.0	2.00%		
Cleveland	2.0	4.2%	8.0	18.60%	5.0	22.73%
Lincoln	2.0	4.2%	4.0	9.30%	2.0	9.09%
Mecklenburg			1.0	2.00%		
Rutherford			1.0	2.00%		
South Carolina			5.0	11.00%	1.0	4.55%
Total	47.7	100.00%	45.1	100.00%	23.3	100.00%

In Section C, pages 25-29, the applicant provides the assumptions and methodology used to project patient origin. The applicant's assumptions are reasonable and adequately supported based on the following:

- The applicant projects patient origin at Fresenius Kidney Care North Gaston based on its historic patient origin as of December 31, 2021.
- The applicant projects the in-center dialysis patient census for residents of Gaston County will increase by 3% per year, which is the average annual change rate as published in the 2022 SMFP by patient population.
- The applicant projects the home hemodialysis and peritoneal dialysis patient census for residents of Gaston County will increase by 3% per year, which is the average annual change rate as published in the 2022 SMFP by patient population.
- The applicant did not project growth in the number of patients at Fresenius Kidney Care North Gaston who do not live in Gaston County.

Analysis of Need

In Section C, pages 30-31, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

“This is an application to develop new dialysis stations, filed in response to the facility needed determination.

Patients with end stage renal disease require dialysis treatment on a regular basis in order to maintain life. Patients will normally receive three treatments per week. The NC SMFP recognizes that this patient population requires frequent and regular treatment. The need methodology for dialysis stations is focused on four patient shifts per week and recognizes that patients will generally dialyze on a Monday-Wednesday-Friday, morning or afternoon shift schedule, or on a Tuesday-Thursday-Saturday morning or afternoon shift schedule. Failure to receive dialysis care will ultimately lead to the patient's demise.

The need that this population has for the proposed services is a function of the individual patient need for dialysis care and treatment. This question specifically addresses the need that the population to be served has for the proposed project.”

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

- Based on application of Condition 1 of the facility need methodology in the 2022 SMFP, the applicant demonstrates the need for up to four additional stations at Fresenius Kidney Care North Gaston.

- The applicant provides supporting documentation in its projected utilization based on the historical growth at Fresenius Kidney Care North Gaston since it became operational in April 2017.

Projected Utilization

- On Form C Utilization subsection in Section Q, the applicant provides historical and projected utilization as illustrated in the following table.

Fresenius Kidney Care North Gaston In-Center Patients

	In-Center Stations	In-Center Patients
The applicant begins with the 40 Gaston County patients dialyzing on 12 stations at the facility as of 12/31/2021.	12	40
Gaston County patient census is projected forward one year to December 31, 2022 using Gaston County five-year average annual change rate (AACR) of 3%.		$40 \times 1.030 = 41.2$
The four patients from outside Gaston County are added to the facility's census. This is the ending census for interim year one.		$41.2 + 4 = 45.2$
Gaston County patient census is projected forward a year and is increased by 3%.		$41.2 \times 1.030 = 42.4$
The four patients from outside Gaston County are added to the facility's census. This is the ending census for the first full fiscal year.		$42.4 + 4 = 46.4$
The facility's patient census is projected forward a year to 12/31/2024 and is increased by 3.0%.		$42.4 \times 1.030 = 43.7$
The four patients from outside Gaston County are added to the facility's census. This is the ending census as of the project's second full fiscal year (FY2).		$43.7 + 4 = 47.7$

Source: Table in Section Q., page 88.

At the end of FY1 (CY2023) the facility is projected to serve 46 in-center patients and at the end of FY2 (CY2024) the facility is projected to serve 48 in-center patients. The projected utilization rates for the first two operating years are as follows:

- By the end of FY1 the facility is projected to have:
 $46 \text{ patients} / 16 \text{ certified stations} = 2.88 \text{ patients} / \text{station/week}$
 $2.88 / 4 = .72$ or 72% utilization rate
- By the end of FY2, the facility is projected to have:
 $48 \text{ patients} / 16 \text{ certified stations} = 3.0 \text{ patients} / \text{station/week}$
 $3.0 / 4 = .75$ or 75.0% utilization rate.

Home Hemodialysis (HHD) Projected Utilization

- The applicant begins its utilization projections with the HHD census on December 31, 2020. On pages 25-28, the applicant states that, on December 31, 2021, its HHD patient census was comprised of 23 Gaston County patients and 15 patients from other North Carolina counties and five from South Carolina.
- The applicant assumes that the HHD patient population will increase by 3.0% as published in the 2022 SMFP patient per year through the second full operating year following project completion. Based on the projected patient origin on page 25, the applicant projects the new patients will be Gaston County residents.
- The project is scheduled to begin offering these projected growth services on January 1, 2023. OY1 is CY 2023. OY2 is CY 2024.

In Section C, page 28, and the Form C Utilization subsection of Section Q, the applicant provides the calculations used to project the HHD patient census for OY1 and OY2, as summarized in the table below.

Fresenius Kidney Care North Gaston Home Hemodialysis

	Home Hemodialysis
The applicant begins with the 23 Gaston County home hemodialysis patients as of 12/31/2021.	23
Gaston County patient census is projected forward one year to December 31, 2022 using Gaston County five-year average annual change rate (AACR) of 3%.	$23 \times 1.030 = 23.7$
The 20 patients from outside Gaston County are added to the home hemodialysis census. This is the ending census for interim year one.	$23.7 + 20 = 43.7$
Gaston County patient census is projected forward one year, December 31, 2023, using the Gaston County Annual Change Rate.	$23.7 \times 1.030 = 24.4$
The 20 patients from outside Gaston County are added to the home hemodialysis facility's census. This is the projected ending census for operating year 1.	$24.4 + 20 = 44.4$
The home hemodialysis patient census is projected forward a year to 12/31/2024 and is increased using the Average Annual Change Rate by 3.0%.	$24.4 \times 1.030 = 25.1$
The 20 patients from outside Gaston County are added to the home hemodialysis facility's census. This is the ending census as of the project's second full fiscal year (FY2).	$25.1 + 20 = 45.1$

Source: Table in Section Q., page 90.

At the end of FY1 (CY2023) the facility is projected to serve 44.4 home hemodialysis patients and at the end of FY2 (CY2024) the facility is projected to serve 45.1 home hemodialysis patients. The projected utilization rates for the first two operating years are as follows:

- By the end of FY1 the facility is projected to have:
44.4 Home Hemodialysis patients.
- By the end of FY2, the facility is projected to have:
45.1 home Hemodialysis patients.

Peritoneal Dialysis (PD) Projected Utilization

- The applicant begins its utilization projections with the PD facility census on December 31, 2020. On page 25, the applicant states that, on December 31, 2021, its PD patient census was comprised of fourteen Gaston County patients and seven patients from other North Carolina counties and one from South Carolina.
- The applicant assumes that the PD patient population will increase by one patient per year through the second full operating year following project completion by applying the Gaston County AARC of 3%. Based on the projected patient origin on page 25, the applicant projects the new patients will be Gaston County residents.
- The project is scheduled to begin offering services on January 1, 2023. OY1 is CY 2023. OY2 is CY 2024.

In Section C, page 29, and the Form C Utilization subsection of Section Q, the applicant provides the calculations used to project the PD patient census for OY1 and OY2, as summarized in the table below.

Fresenius Kidney Care North Gaston Peritoneal Dialysis

	Peritoneal Dialysis
The applicant begins with the 14 Gaston County Peritoneal Patients as of 12/31/2021.	14
Gaston County patient census is projected forward one year to December 31, 2022 using Gaston County five-year average annual change rate of 3%.	$14 \times 1.030 = 14.4$
The 8 patients from outside Gaston County are added to the Gaston County census. This is the ending census for interim year one.	$14.4 + 8 = 22.4$
Gaston County patient census is projected forward one year, December 31, 2023, using the Gaston County Annual Change Rate.	$14.4 \times 1.030 = 14.9$
The 8 patients from outside Gaston County are added to the Gaston County patient census. This is the projected ending census for operating year 1.	$14.9 + 8 = 22.9$
The facility's patient census is projected forward a year to 12/31/2024 and is increased using the AACR of 3.0%.	$14.9 \times 1.030 = 15.3$
The 8 patients from outside Gaston County are added to the Gaston County patient census. This is the ending census as of the project's second full fiscal year (FY2).	$15.3 + 8 = 23.3$

Source: Table in Section Q., page 91.

At the end of FY1 (CY2023) the facility is projected to serve 14 Peritoneal dialysis patients and at the end of FY2 (CY2024) the facility is projected to serve 23.3 Peritoneal dialysis The projected utilization rates for the first two operating years are as follows:

- By the end of FY1 the facility is projected to have:
22.9 Peritoneal dialysis patients.
- By the end of FY2, the facility is projected to have:
23.3 Peritoneal dialysis patients.

The projected utilization exceeds the 2.8 in-center patients per station threshold per week for the first year following completion of the project, as required by 10A NCAC 14C.2203 (b).

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

- Applicant projects growth using Gaston County Five Year Average Annual Change Rate (AACR) of 3.0 percent as published in the 2022 SMFP.
- With the certification of four additional stations, utilization increased at Fresenius Kidney Care North Gaston in 2021. The applicant states that it ended 2021 with 40 in-center

patients and 12 certified stations, which is a utilization rate of 3.33 patients per station per week or 83.3 percent (40 patients / 12 stations = 3.33 patients per station per week; $3.33 / 4 = 0.833$ or 83.3%).

- The applicant states its projected utilization demonstrates the proposed four stations will be well-utilized.
- The applicant states the facility is serving 43 home hemodialysis patients and 22 peritoneal dialysis patients. Patients will continue to receive services from Fresenius Kidney Care North Gaston.
- The applicant uses publicly available information it has reported to the Agency in the past to demonstrate the historical growth rate at the facility.
- The applicant demonstrates the need for the additional four stations while using the 2022 SMFP projected growth rate for the facility.
- The applicant provides information about the need to continue to offer home Peritoneal and Hemodialysis dialysis services.
- The applicant assumes no population growth for the patients residing in other North Carolina counties dialyzing but assumes the patients will continue to dialyze in-center and adds them to the calculations when appropriate.
- The project is scheduled to begin offering services on January 1, 2023. OY1 is CY 2023. OY2 is CY 2024.

Access to Medically Underserved Groups

In Section C, pages 34, the applicant states:

“... Fresenius Medical Care, has a long history of providing dialysis services to the underserved population of North Carolina...”

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

The applicant provides the estimated percentage of total patients for each medically underserved group during the second full fiscal year, as shown in the following table.

Medically Underserved Groups	Estimated % of Total Patients in FY 2
Low income persons	54.5%
Racial and ethnic minorities	56.8%
Women	45.5%
Persons with disabilities	50.0%
Persons 65 and older	52.3%
Medicare beneficiaries	88.6%
Medicaid recipients	54.5%

Source: Section C, page 34

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

- The applicant provides a statement saying it will provide service to all residents of the service area, including underserved groups, without regard for anything other than the need for dialysis services.
- The applicant states it assumes the percentages of patients for each group listed above would be consistent with historical utilization at its facility.

Conclusion

The Agency reviewed the:

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

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

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

NA

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

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

CA

The applicant proposes to add four dialysis stations to Fresenius Kidney Care North Gaston, pursuant to Condition 1 of the facility need methodology, for a total of 16 stations upon project completion.

In Section E, page 43, 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, *“if the applicant had chosen to not apply for additional stations, utilization on 12 stations would be projected to be 3.86 patients per station at the end of Operating Year 1, and 3.98 patients per station at the end of Operating Year 2. Failure to apply for additional stations leads to higher utilization rates, potentially interrupts patient admissions to the facility and is the least effective alternative.”*
- Apply for fewer than four stations. The applicant states, *“that this would have the same effect as not applying higher rates as the facility patient census increases. This is not the most effective alternative.”*
- Apply for more than four stations. The applicant states, *“an application for more than four stations is not cost effective. The applicant does not have the space for more than 16 total dialysis stations in the facility. Even though the facility qualifies to apply for as many as 16 dialysis stations, there is no room for more than four additional stations.”*

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

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

Conclusion

The Agency reviewed the:

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

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

1. **Bio-Medical Applications of North Carolina, Inc. (hereinafter the certificate holder) shall materially comply with all representations made in the certificate of need application.**
 2. **Pursuant to Condition 1 of the facility need determination in the 2022 SMFP, the certificate holder shall develop no more than four additional in-center dialysis stations for a total of no more than 16 in-center dialysis stations at Fresenius Kidney Care North Gaston upon project completion.**
 3. **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.**
 4. **Progress Reports:**
 - a. **Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. **The certificate holder shall complete all sections of the Progress Report form.**
 - c. **The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. **The first progress report shall be due on October 1, 2022**
 5. **The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

Add no more than four dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 16 dialysis 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.

Form F.1a Capital Cost	Applicant 1 Bio-Medical Application of North Carolina, Inc.
Non-Medical Equipment	\$3,000
Furniture	\$12,000
Total Capital Cost	\$15,000

In Section Q, page 94, the applicant provides the assumptions used to project the capital cost.

In Section F, page 45-47, the applicant states that there will be no start-up or initial operating expenses associated with the proposed project since it is an existing facility that is already operational.

Availability of Funds

In Section F. 2, page 45, 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 *	\$15,000	\$15,000
Bonds	\$0	\$0
Other (Specify)	\$ 0	\$0
Total Financing	\$15,000	\$15,000

* OE = Owner's Equity

Exhibit F-2 contains a letter from the applicant on behalf of the Vice President & Treasurer of Fresenius Medical Care Holdings, Inc, authorizing the use of accumulated reserves for the capital needs and any other needs of the project.

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

- The applicant provided a letter from an appropriate company official committing the amount of the projected capital cost to the proposed project.
- The applicant provided publicly available documentation of its available cash and assets it will use to fund the projected capital cost of the proposed project.

Financial Feasibility

The applicant provides pro forma financial statements for the first two full fiscal years of operation following completion of the project. On form F.2 in Section Q, the applicant projects that revenues will exceed operating expenses in the first two full fiscal years following completion of the project, as shown in the table below.

Projected Revenues and Operating Expenses		
FKC North Gaston	Full Fiscal Year 1 CY 2023	Operating Year 2 CY 2024
Total Treatments	16,619	17,007
Total Gross Revenues (Charges)	\$104,549,300	\$106,993,344
Total Net Revenue	\$6,409,554	\$6,560,068
Average Net Revenue per Treatment	\$386	\$386
Total Operating Expenses (Costs)	\$4,479,218	\$4,562,078
Average Operating Expense per Treatment	\$270	\$268
Net Income/(Loss)	\$1,930,337	\$1,997,990

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

- The applicant adequately explains the assumptions used to project revenue, such as projected reimbursement rates, and operating costs, such as salaries.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described 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 all the reasons described 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

Add no more than four dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 16 dialysis stations upon project completion.

On page 115, the 2022 SMFP defines the service area for dialysis stations as “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.” Thus, the service area is Gaston County. Facilities may serve residents of counties not included in their service area.

The table below lists the existing and approved facilities, certified stations, and utilization of dialysis facilities in Gaston County as of December 31, 2020. The applicant owns and operates five dialysis facilities in Gaston County. The applicant is the only provider of dialysis services in Gaston County.

Gaston County Dialysis Facilities

Facility Name	Certified Stations as of 12/31/2020	# of In-center Patients as of 12/31/2020	Utilization by Percent as of 12/31/2020
BMA Kings Mountain	22	63	75.00%
Fresenius Kidney Care North Gaston	12	22	45.83%
Fresenius Medical Care Belmont	19	70	92.11%
Fresenius Medical Care Gastonia	39	123	78.85%
Fresenius Medical Care South Gaston	28	74	66.07%

Source: SMFP 2022, Table 9A

In Section G, page 52, 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:

“BMA is the only dialysis provider of in-center dialysis services in Gaston County. This application is to add four dialysis stations to an existing dialysis facility based upon the performance and demonstrated need at the Fresenius Kidney Care North Gaston facility. The need addressed by this application is not specific to Gaston County as a whole. The stations are needed by the patient population to be served by the facility. The projections of the future patient population to be served begins with the current patient population of the facility and an increase of that population at a rate of 3.0%. The applicant has not projected to serve patients currently served in another facility or served by another provider. These stations are needed to support the growing patient census at the Fresenius Kidney Care North Gaston facility. Given the utilization and growth of the facility, BMA does not believe adding four stations will

duplicate any services. Rather, the additional stations will ensure continued adequate access to dialysis care for the patient population of the area.

Further, four of the five dialysis facilities operating in Gaston County, all BMA facilities were operating at or above the 75% utilization threshold as of December 31, 2021. The overall utilization for facilities in Gaston County was 76.49%, or 3.06 patients per station as of December 31, 2021.”

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

- The applicant proposes to increase the number of dialysis stations in Gaston County based on Condition 1 of the facility need determination in the 2022 SMFP.
- The applicant adequately demonstrates that the proposed dialysis stations are needed in addition to the existing or approved dialysis stations in Gaston County.

Conclusion

The Agency reviewed the:

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

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

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

C

Add no more than four dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 16 dialysis stations upon project completion.

In Section Q, Form H, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Current FTE Staff	Projected FTE Staff
	As of 2/17/2022	2nd Full Operating Year CY 2024
Administrator	1.00	1.00
Registered Nurse (RNs)	2.00	2.00
Home Training Nurses	3.00	3.00
Technicians (PCT)	5.00	5.00
Dietician	0.50	0.50
Social Worker	0.50	0.50
Maintenance	0.50	0.50
Administration/Business Office	1.00	1.00
Other: (Director of Operations)	0.20	0.20
Other: (FMC Chief Technician)	0.20	0.20
Other: (FMC In-Service)	0.15	0.15
TOTAL	14.05	14.05

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.4, which is found in Section Q. In Section H.2 and H.3, pages 55 and 56, respectively, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

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

- The applicant projects sufficient operating expenses for the staff proposed by the applicant.
- The applicant provides examples of its required qualifications for staff, continuing education, and other training programs.

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.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise plan 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

Add no more than four dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 16 dialysis stations upon project completion.

Ancillary and Support Services

In a table in Section I, page 57, the applicant identifies the ancillary and support services necessary for the proposed services. On pages 57- 62 the applicant explains how each ancillary and support service is made available.

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

- The applicant currently provides dialysis services at Fresenius Kidney Care North Gaston.
- The applicant describes how it provides these services at the existing facility.

Coordination

In Section I, page 57, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I-2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The facility is an existing facility that has existing relationships with local health care and social service providers.
- The applicant provides a letter from the facility administrator identifying existing relationships with specific local health care and social service providers.
- The applicant provides a letter from the medical director of the facility attesting to the relationship between the medical director's physician practice and the facility.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

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

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

NA

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

- (11) Repealed effective 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 70, the applicant provides the historical payor mix during last full operating year (CY 2021) of the proposed services, as shown in the table below.

Fresenius Kidney Care North Gaston –Payor Mix						
County	Last FY as of 12/31/2021					
	In-Center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-Pay	3.5	7.97%	1.0	2.31%	0.1	0,30%
Insurance	0.9	2.09%	8.1	18.77%	6.8	31.03%
Medicare	33.9	76.96%	33.7	78.30%	14.1	64.25%
Medicaid	4.8	10.84%	0.3	0.62%	0.3	1.56%
Other (Misc.SC)	0.9	2.14%	0.0	0.00%	0.6	2.86%
Total	44.0	100.00%	43.0	100.00%	22.0	100.0%

In Section L, page 69, the applicant provides the following comparison.

Fresenius Kidney Care North Gaston	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	45.5%	51.7%
Male	54.5%	48.3%
Unknown	0.0%	0.0%
64 and Younger	47.7%	83.7%
65 and Older	52.3%	16.3%
American Indian	0.0%	0.6%
Asian	0.0%	1.6%
Black or African - American	43.2%	17.9%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	47.7%	71.1%
Other Race	9.1%	9.8%
Declined / Unavailable	0.0%	0.0%

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

C

Add no more than four dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 16 dialysis stations upon project completion.

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 72, the applicant states it has no such obligation.

In Section L, page 72, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against the facility.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

– Projected Payor Mix (CY 2024)						
	In-Center Patients		Home Hemodialysis Patients		Peritoneal Dialysis Patients	
Payor Source	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-Pay	3.8	7.97%	1.0	2.31%	0.1	0.30%
Insurance*	1.0	2.09%	8.5	18.77%	7.2	31.03%
Medicare*	36.7	76.96%	35.3	78.30%	15.0	64.25%
Medicaid*	5.2	10.84%	0.3	0.62%	0.4	1.56%
Other (VA)	1.0	0.00%	0.0	0.00%	0.7	2.86%
Total	47.7	100.00%	45.1	100.0%	23.3	100.00%

Table may not foot due to rounding.

*Including any managed care plans.

In Section L, page 75, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

As shown in the table above, during the second full fiscal year following project completion, the applicant projects that 7.97% of in-center (IC) dialysis services, 2.31% of HHD services and 0.30% of PD services will be provided to self-pay patients; 76.96%, 78.3% and 64.25% of IC, HHD and PD services, respectively, will be provided to Medicare patients; and 10.84%, 0.62% and 1.56% of IC, HHD and PD services, respectively, will be provided to Medicaid patients.

On page 73, the applicant provides the assumptions and methodology it uses 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 because it is based on the historical payor mix.

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 reasons stated above.

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

C

In Section L, page 75, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

Add no more than four dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 16 dialysis stations upon project completion.

In Section M, page 76, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.1. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following:

- The applicant provides a copy of a letter sent to Gaston College offering the facility as a training site for nursing students.
- The letter provided by the applicant was sent several years ago and thus indicates the facility has been providing such access prior to this application.

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.

- (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

Add no more than four dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 16 dialysis stations upon project completion.

On page 115, the 2022 SMFP defines the service area for dialysis stations as “*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.*” Thus, the service area is Gaston County. Facilities may serve residents of counties not included in their service area.

The table below lists the existing and approved facilities, certified stations, and utilization of dialysis facilities in Gaston County as of December 31, 2020. The applicant owns and operates five dialysis facilities in Gaston County. The applicant is the only provider of dialysis services in Gaston County.

Facility Name	Certified Stations as of 12/31/2020	# of In-center Patients as of 12/31/2020	Utilization by Percent as of 12/31/2020
BMA Kings Mountain	22	63	75.00%
Fresenius Kidney Care North Gaston	12	22	45.83%
Fresenius Medical Care Belmont	19	70	92.11%
Fresenius Medical Care Gastonia	39	123	78.85%
Fresenius Medical Care South Gaston	28	74	66.07%

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 77, 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. The projected patient population for the facility begins with the current patient population, projected patient transfers, and growth of that population consistent with the Gaston County Five Year Average Annual Change Rate published in the 2022 SMFP.”

Regarding the impact of the proposal on cost effectiveness, quality, and access by medically underserved groups, in Section N, page 77, the applicant states:

“Approval of this application will allow the facility 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.”

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

“Fresenius related facilities in NC have historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for being an underserved person. Low income and medically underserved persons will continue to have access to all services provided by Fresenius related facilities.”

See also Sections B, C, F, L, O, and Q 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.
- 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 all the reasons described 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

Add no more than four dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 16 dialysis stations upon project completion.

On Form O, pages, 107-111 in Section Q, 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 108 existing or approved kidney disease treatment facilities located in North Carolina.

In Section O, page 83, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents resulting in an Immediate Jeopardy violation that 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 108 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 Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The application is conforming to all applicable criteria, as 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 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, 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.

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

(1) an existing dialysis facility; or

(2) a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need; shall document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the additional stations.

-C-

In Section C, page 27 the applicant projects Fresenius Kidney Care North Gaston will serve 46.4 patients on 16 stations. (46 patients / 16 certified stations = 2.88 in-center patients per station per week as of the end of the first full operating year (CY2023) following project completion. This meets the minimum performance standard requirement of 2.8 patients per station per week. The discussion regarding projected utilization found in Criteria (3) is incorporated herein by reference.

(c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.

-C-

In Section C, pages 26-29, and Section Q, Form C, the applicant provides the assumptions and methodology it uses to project utilization of the facility.