

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: October 14, 2020

Findings Date: October 14, 2020

Project Analyst: Misty L. Piekaar-McWilliams

Team Leader: Gloria C. Hale

Project ID #: F-11936-20

Facility: BMA Albemarle

FID #: 955784

County: Stanly

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

Project: Add no more than 3 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 29 stations upon completion

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications of North Carolina, Inc. (BMA or “the applicant”) proposes to add no more than three (3) dialysis stations to BMA Albemarle pursuant to Condition 2 of the facility need methodology for a total of no more than 29 stations upon completion of this project. Bio-Medical Applications of North Carolina, Inc. is a wholly owned subsidiary of Fresenius Medical Care Holdings, Inc. (FMC or Fresenius). BMA Albemarle provides in-center (IC) dialysis as well as both a home hemodialysis (HH) program and a peritoneal dialysis (PD) program.

Need Determination

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 Stanly 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 dialysis center 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 Albemarle on page 163 of the 2020 SMFP is 76.92 percent or 3.0769 patients per station per week, based on 80 in-center dialysis patients and 26 certified dialysis stations (80 in-center patients / 26 dialysis stations = 3.0769; $3.0769 / 4 = 76.92\%$).

As shown in Table 9E, page 173 of the 2020 SMFP, based on the facility need methodology for dialysis stations, the potential number of stations needed at BMA Albemarle is up to four (4) additional stations; thus, the applicant is eligible to apply to add up to four (4) dialysis stations during the 2020 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than three (3) new dialysis stations to BMA Albemarle, which is less than the proposed number of stations permitted to be added at BMA Albemarle pursuant to Condition 2 of the facility need methodology in the 2020 SMFP; 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 which is applicable to this review. *Policy GEN-3: Basic Principles*, on 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 will promote safety and quality in Section B, page 15; Section N, page 52; Section O, pages 54-57; and referenced exhibits.

The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal will promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project will promote equitable access in Section B, pages 15-17; Section C, pages 24-25; Section L, pages 46-49; Section N, pages 51-53; and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal will promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project will maximize healthcare value in Section B, page 16; Section F, pages 31-35; Section N, pages 51-53; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant's proposal will maximize healthcare value.

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

Conclusion

The Agency reviewed the:

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

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

- The application is consistent with Condition 2 of the facility need methodology for dialysis stations.
- The application is consistent with Policy GEN-3.

(2) Repealed effective July 1, 1987.

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

C

The applicant proposes to add no more than three (3) dialysis stations to BMA Albemarle pursuant to Condition 2 of the facility need methodology for a total of no more than 29 stations upon completion of this project.

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 and Graham counties and Avery, Mitchell, and Yancey counties.” BMA Albemarle is in Stanly County. Thus, the service area for this facility consists of Stanly County. Facilities may serve residents of counties not included in their service area.

The following table illustrates current and projected patient origin.

In Section C.2, page 19, the applicant provides the patient origin for BMA Albemarle’s IC, HH and PD patients as of December 31, 2019, as summarized in the table below.

**BMA Albemarle
 1/1/2019 to 12/31/2019**

COUNTY	# OF IC PATIENTS	% IC Total	# of HH Patients	% HH Total	# of PD Patients	% PD Total
Stanly	66.0	88.0%	1.0	50.0%	10.0	66.7%
Anson	0.0	0.0%	0.0	0.0%	1.0	6.7%
Cabarrus	0.0	0.0%	0.0	0.0%	3.0	20.0%
Montgomery	2.0	2.7%	0.0	0.0%	0.0	0.0%
Richmond	3.0	4.0%	0.0	0.0%	0.0	0.0%
Rowan	3.0	4.0%	1.0	50.0%	0.0	0.0%
Scotland	0.0	0.0%	0.0	0.0%	1.0	6.7%
Wake	1.0	1.3%	0.0	0.0%	0.0	0.0%
Total	75.0	100.0%	2.0	100.0%	15.0	100.0%

Totals may not sum due to rounding

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

BMA Albemarle
1/1/2023 to 12/31/2023

COUNTY	# OF IC PATIENTS	% IC Total	# of HH Patients	% HH Total	# of PD Patients	% PD Total
Stanly	83.2	90.2%	3.3	62.5%	10.0	90.9%
Anson	0.0	0.0%	0.0	0.0%	1.0	9.1%
Cabarrus	1.0	1.1%	0.0	0.0%	0.0	0.0%
Mecklenburg	0.0	0.0%	1.0	18.8%	0.0	0.0%
Montgomery	2.0	2.2%	0.0	0.0%	0.0	0.0%
Richmond	3.0	3.3%	0.0	0.0%	0.0	0.0%
Rowan	3.0	3.3%	1.0	18.8%	0.0	0.0%
Total	92.2	100.0%	5.3	100.0%	11.0	100.0%

Totals may not sum due to rounding

In Section C, pages 20-22, and the Form C Utilization subsection of Section Q, the applicant provides the assumptions and methodology used to project patient origin. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.4, page 23, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

“Patients with End Stage Renal Disease require dialysis treatment on a regular and consistent basis in order to maintain life. As a general rule, patients will 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.”

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

- According to the 2020 SMFP, as of December 31, 2018, BMA Albemarle was operating at a rate of 3.0769 patients per station per week, or 76.92 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 need methodology found in Criterion (1) is incorporated herein by reference.

- The applicant projects a utilization rate of 3.09 in-center patients per station per week dialyzing at BMA Albemarle as of the end of the first 12 months of operation following certification of the additional stations which exceeds the performance standard 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 Patients

In Section C, pages 19-22, and in Section Q, pages 68-69, the applicant provides projected utilization, as illustrated in the following table.

BMA ALBEMARLE IN-CENTER PATIENTS	
Begin with facility census of Stanly County patients as of June 30, 2020.	75
Project the Stanly County patients forward for six months to December 31, 2020, using one half of the Stanly County Five Year Average Annual Change Rate (AACR) of 3.0% (6 months is 1.5%)	$75 \times 1.015 = 76.1$
Project Stanly County patient population forward one year to December 31, 2021, using the Stanly County Five Year AACR of 3.0%.	$76.1 \times 1.03 = 78.4$
Add patients residing from other counties. This is the projected starting census for this project.	$78.4 + 9 = 87.4$
Project the Stanly County patient population forward one year to December 31, 2022, using the Stanly County Five Year AACR of 3.0%.	$78.7 \times 1.03 = 80.8$
Add patients residing from other counties. This is the projected ending census for Operating Year 1 (OY1).	$80.8 + 9 = 89.8$
Project the Stanly County patient population forward one year to December 31, 2023, using the Stanly County Five Year AACR of 3.0%.	$80.8 \times 1.03 = 83.2$
Add patients residing from other counties. This is the projected ending census for Operating Year 2 (OY2).	$83.2 + 9 = 92.2$

Note: The applicant incorrectly listed the Stanly County patient population as 78.7 and not 78.4 when projecting the Stanly County population at the end of December 31, 2022. However, this error did not affect any calculations for projected in-center methodology.

In both Section C, pages 19-22, and Section Q, pages 68-71, 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 Albemarle patient census as of June 30, 2020, which was 84 total IC patients: 75 Stanly County patients, one (1) Cabarrus County patient, two (2) Montgomery County patients, three (3) Richmond County patients, and three (3) Rowan County patients.

- The Cabarrus, Montgomery, Richmond and Rowan County patients will be carried forward into projections of future patient census however, the applicant does not project any growth of the Cabarrus, Montgomery, Richmond and Rowan County patients.
- The applicant projects the facility patients who reside in Stanly County will grow at the Five Year Average Annual Change Rate for Stanly County, 3.0%, as stated in Table 9C: ESRD Dialysis Station Need Determinations by Planning Area, page 168, of the 2020 SMFP.

At the end of OY1 (CY2022) BMA Albemarle is projected to serve 89.8 in-center patients on 29 stations; and at the end of OY2 (CY2023) the facility is projected to serve 92.2 in-center patients on 29 stations.

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

- OY1: 3.09 patients per station per week, or 77.25% utilization [$89.8 / 29 = 3.09$; $3.09 / 4 = 0.7725$ or 77.25%].
- OY 2: 3.17 patients per station per week, or 79.25% utilization [92.2 patients / 29 stations = 3.17 ; $3.17 / 4 = 0.7925$ or 79.25%].

The projected utilization of 3.09 patients per station per week at the end of OY1 exceeds the minimum standard of 2.8 in-center patients per station per week required by 10A NCAC 14C .2203(b).

Projected utilization 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 3.0 percent for Stanly County patients which reflects the Stanly County Five Year AACR as published in Table 9C of the 2020 SMFP.
- The applicant conservatively does not project growth for its Cabarrus, Montgomery, Richmond and Rowan County patients.
- The applicant demonstrated that the existing and approved stations are inadequate to serve the current and projected patient population.
- Projected utilization at the end of OY1 exceeds the minimum of 2.8 patients per station per week required by 10A NCAC 14C .2203(b).

Peritoneal and Home Hemodialysis Patients

In both Section C, pages 21-22, and Section Q, pages 68-69, 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 Albemarle PD and HH patient census as of June 30, 2020, which was:
 - 5 total HH patients: three (3) Stanly County patients, one (1) patient from Mecklenburg County and one (1) patient from Rowan County.
 - 10 total PD patients: nine (9) Stanly County patients and one (1) patient from Anson County.
- The non-Stanly County PD and HH patients will be carried forward into projections of future patient census however, the applicant does not project any growth of the non-Stanly County PD and HH patients.
- The applicant projects the facility patients who reside in Stanly County will grow at the Five Year AACR for Stanly County, 3.0%, as stated in Table 9C: ESRD Dialysis Station Need Determinations by Planning Area, page 168, of the 2020 SMFP.

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 3.0 percent for Stanly County patients which reflects the Stanly County Five Year AACR as published in Table 9C of the 2020 SMFP.
- The applicant conservatively does not project growth for its non-Stanly County PD and HH patients.

Access

In Section C.7, page 24, 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.”

In Section L, page 48, 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.

**BMA Albemarle
 Projected Payor Mix CY 2023**

Payor Source	In-Center		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	0.4	0.39%	0.00	0.00%	0.02	0.17%
Insurance*	1.8	1.93%	4.18	78.42%	2.28	20.80%
Medicare*	60.3	65.45%	0.21	3.86%	5.89	53.62%
Medicaid*	6.6	7.12%	0.00	0.00%	0.00	0.00%
Medicare/Commercial	20.2	21.87%	0.94	17.72%	2.39	21.73%
Miscellaneous (Incl. VA)	3.0	3.24%	0.00	0.00%	0.40	3.68%
Total	92.2	100.00%	5.33	100.00%	10.98	100.00%

*Including any managed care plans

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

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

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

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

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

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 three (3) dialysis stations to BMA Albemarle pursuant to Condition 2 of the facility need methodology for a total of no more than 29 stations upon completion of this project.

In Section E, page 30, 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 maintaining the status quo would not be responsive to the growth of the patient census; therefore, this is not an effective alternative.
- Apply for Fewer than Three (3) Stations: the applicant states applying for fewer stations would also not be responsive to the growth of the patient census; therefore, this is not an effective alternative.

On page 30, the applicant states its proposal is the most effective alternative because the growth of the patient census requires the facility to add stations.

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

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides 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. **BMA Albemarle (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application and any supplemental responses. If representations conflict, the certificate holder shall materially comply with the last made representation.**
 2. **Pursuant to Condition 2 of the facility need determination in the 2020 SMFP, the certificate holder shall develop no more than 3 additional in-center dialysis (and home hemodialysis) stations for a total of no more than 29 in-center stations at BMA Albemarle upon completion of this project.**
 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.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

BMA Albemarle proposes to add no more than three (3) dialysis stations to BMA Albemarle pursuant to Condition 2 of the facility need methodology for a total of no more than 29 stations upon completion of this project.

Capital and Working Capital Costs

In Section F, page 31, and on Form F.1a in Section Q, page 72, the applicant projects the total capital cost of the project as shown in the table below.

Projected Capital Costs	
	Total Costs
Construction/Renovation Costs	\$131,967
Non-Medical Equipment	\$7,260
Other: Contingency	\$19,795
Total Capital Cost	\$159,022

In Section Q, the applicant provides the assumptions used to project the capital cost to ensure project costs are reasonable.

In Section F, pages 32-33, the applicant states there are no projected working capital costs because it is an existing facility that is already operational.

Availability of Funds

In Section F, page 31, 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 *	\$159,022	\$159,022
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$ 159,022	\$159,022

* OE = Owner's Equity

Exhibit F-2 contains a letter dated August 17, 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 original letter dated August 17, 2020, and subsequent clarifying letter dated October 1, 2020, state that the Consolidated Balance Sheet from Fresenius Medical Care Holdings, Inc., for year ending December 31, 2019, show that Fresenius Medical Care Holdings, Inc. had \$446 million in cash and over \$25 billion in total assets to fund the capital cost of the proposed project.

The original letter of financial commitment dated August 17, 2020, stated Fresenius will commit up to \$11,250 towards the cost of the project despite the application stating expected capital expenditures will total \$159,022. In response to a request for clarifying information from the Agency, the applicant has submitted a corrected letter of financial commitment to the Agency stating Fresenius will provide for the full amount of the project up to \$159,022.

Financial Feasibility

The applicant provides pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Section Q, Form F.2, 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		
BMA Albemarle	Full Fiscal Year 1 CY 2022	Full Fiscal Year 2 CY 2023
Total Treatments	15,439	15,849
Total Gross Revenues (Charges)	\$97,127,582	\$99,706,225
Total Net Revenue	\$4,623,107	\$4,741,724
Average Net Revenue per Treatment	\$299.44	\$299.18
Total Operating Expenses (Costs)	\$4,394,397	\$4,342,277
Average Operating Expense per Treatment	\$284.63	\$273.98
Net Income/Profit	\$228,710	\$399,447

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion 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.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

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

C

BMA Albemarle proposes to add no more than three (3) dialysis stations to BMA Albemarle pursuant to Condition 2 of the facility need methodology for a total of no more than 29 stations upon completion of this project.

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 Albemarle is in Stanly county. Thus, the service

area for this facility consists of Stanly County. Facilities may serve residents of counties not included in their service area.

According to Table 9B of the 2020 SMFP, BMA Albemarle is the only existing or approved dialysis facility in Stanly County. Information from Table 9B of the 2020 SMFP, is provided below:

Stanly County Dialysis Facilities

Dialysis Facility	Certified Stations	Percent Utilization	Patients Per Station
BMA Albemarle	26	76.92%	3.08

Source: 2020 SMFP, Table 9B, page 163

In Section G, page 36, the applicant explains why it believes the proposal would not result in the unnecessary duplication of existing or approved dialysis services in Stanly County. The applicant states the additional stations are needed to support the growing patient census at the facility. The applicant also states the stations are for patients being served by this facility, not for patients being served by another provider, and states the projected growth of the patient census is based on the Stanly County Five Year AACR.

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, as calculated using the methodology in the 2020 SMFP, for the proposed dialysis stations.
- 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
- 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

In Section Q, Form H, page 84, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Current FTE Staff	Projected FTE Staff	Projected FTE Staff
	As of 8/2020	1 st Full Operating Year (1/1/2022 to 12/31/2022)	2 nd Full Operating Year (1/1/2023 to 12/31/2023)
Administrator	1.00	1.00	1.00
Registered Nurses (RNs)	4.00	4.00	4.00
Home Training Nurse	2.00	2.00	2.00
Technicians (PCT)	11.00	14.00	14.00
Dietician	1.00	1.00	1.00
Social Worker	1.00	1.00	1.00
Maintenance	1.00	1.00	1.00
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	22.45	25.45	25.45

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, page 37, the applicant describes the methods it uses to recruit or fill new positions and its existing training and continuing education programs. In Section H, page 38, the applicant identifies the current medical director. In Exhibit H-4, the applicant provides a letter from the current medical director indicating his support for the proposed project and his intent to continue serving as medical director for the facility.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

In Section I, page 39, the applicant states the following ancillary and support services are necessary for the proposed services, and explains how each ancillary and support service is made available:

BMA ALBEMARLE ANCILLARY AND SUPPORT SERVICES	
SERVICES	PROVIDER
Self-care training	Provided by the facility
Home training Home Hemodialysis Home Peritoneal dialysis Accessible follow-up program	
Isolation for hepatitis B positive patients	
Nutritional counseling	
Social Work services	
Laboratory services	
Laboratory services	
Vascular surgery	Referral to Southeast Surgical Associates, or Sanger Heart and Vascular
Pediatric nephrology	Referral to Atrium Health – Levine Children’s Hospital in Charlotte
Acute dialysis in an acute care setting	Referral to Atrium Health - Cabarrus
Transplantation services	Referral to Atrium Health – Charlotte, or Wake Forest Baptist Hospital
Emergency Care	Provided by facility staff until ambulance arrival
Blood bank services	Referral to CMC Atrium Stanly County
X-Ray, Diagnostic and evaluation services	Referral to CMC Atrium Stanly County
Psychological counseling	Referral to Daymark Services Albemarle
Vocational Rehabilitation counseling and services	Referral to Vocational Rehabilitation of Stanly County

In Section I, page 40, the applicant describes its existing relationships with other local health care and social service providers.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

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

- (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.

C

In Section K, page 42, the applicant states that the project involves renovating 360 square feet of existing space. Line drawings are provided in Exhibit K-2.

On page 42, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal.

On page 43, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

In Section K, pages 43-44, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

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.

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

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

C

In Section L, page 47, the applicant provides the historical payor mix for BMA Albemarle patients during the last full operating year (CY2019) for the proposed services, as shown in the table below.

**BMA Albemarle
 Historical Payor Mix CY 2019**

Payor Source	In-Center		HOME HEMODIALYSIS		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	.29	0.39%	0.00	0.00%	0.03	0.17%
Insurance*	1.45	1.93%	1.57	78.42%	3.12	20.80%
Medicare*	49.09	65.45%	0.08	3.86%	8.04	53.62%
Medicaid*	5.34	7.12%	0.00	0.00%	0.00	0.00%
Medicare/Commercial	16.40	21.87%	0.35	17.72%	3.26	21.73%
Miscellaneous (Incl. VA)	2.43	3.24%	0.00	0.00%	0.55	3.68%
Total	75.00	100.00%	2.00	100.00%	15.00	100.00%

*Including any managed care plans

In Section L, page 46, the applicant provides the following comparison.

	Percentage of Total Patients Served (All Modalities Combined) CY2019	Percentage of the Population of the Service Area
Female	42.4%	50.1%
Male	57.6%	49.9%
Unknown		
64 and Younger	83.8%	80.7%
65 and Older	16.2%	19.3%
American Indian	0.0%	0.5%
Asian	1.0%	2.0%
Black or African-American	46.5%	11.4%
Native Hawaiian or Pacific Islander	0.0%	0.3%
White or Caucasian	47.5%	80.8%
Other Race	2.0%	5.0%
Declined / Unavailable	3.0%	

The Agency reviewed the:

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

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, the applicant states in Section L.2(a), pages 47-48, that it has no obligation in any of its facilities to provide uncompensated care, community service, or access by minorities and handicapped persons.

In Section L.2(c), page 48, 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.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 48, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

**BMA Albemarle
 Projected Payor Mix CY 2023**

Payor Source	In-Center		HOME HEMODIALYSIS		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	0.4	0.39%	0.00	0.00%	0.02	0.17%
Insurance*	1.8	1.93%	4.18	78.42%	2.28	20.80%
Medicare*	60.3	65.45%	0.21	3.86%	5.89	53.62%
Medicaid*	6.6	7.12%	0.00	0.00%	0.00	0.00%
Medicare/Commercial	20.2	21.87%	0.94	17.72%	2.39	21.73%
Miscellaneous (Incl. VA)	3.0	3.24%	0.00	0.00%	0.40	3.68%
Total	92.2	100.00%	5.33	100.00%	10.98	100.00%

*Including any managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 0.39% of IC services will be provided to self-pay patients, 87.32% to Medicare patients (includes Medicare and Medicare/Commercial), and 7.12% to Medicaid patients.

On page 49, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project.

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

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 49, 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

In Section M, page 50, 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.

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

BMA Albemarle proposes to add no more than three (3) dialysis stations to BMA Albemarle pursuant to Condition 2 of the facility need methodology for a total of no more than 29 stations upon completion of this project.

On page 113, the 2020 SMFP defines the service area for the county need methodology for dialysis stations as “*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service area: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancey counties.*” BMA Albemarle is in Stanly County. Thus, the service area for this application is Stanly County. Facilities may serve residents of counties not included in their service area.

According to Table 9B of the 2020 SMFP, BMA Albemarle is the only existing or approved dialysis facility in Stanly County. Information from Table 9B of the 2020 SMFP, is provided below:

Stanly County Dialysis Facilities

Dialysis Facility	Certified Stations	Percent Utilization	Patients Per Station
BMA Albemarle	26	76.92%	3.07

Source: 2020 SMFP, Table 9B, page 163

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 51, the applicant states:

“The applicant does not expect this proposal to have any effect on the competitive climate in Stanly County. The applicant does not project to serve dialysis patients currently being served by another provider. . . BMA Albemarle is the only dialysis facility within Stanly County”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 52, the applicant states:

“Approval of this application will allow the BMA Albemarle 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.”

Regarding the impact of the proposal on quality, in Section N, page 52, the applicant states:

“Quality 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.’”

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 52, the applicant states:

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

Considering all the information in the application, 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 (see Sections C, F, N and Q of the application and any exhibits)
- Quality (see Sections C, N and O of the application and any exhibits)
- Access to medically underserved groups (see Sections C, L and N of the application and any exhibits)

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 126 dialysis facilities owned, operated, or managed by the applicant or a related entity located in North Carolina.

In Section O.2, page 57, 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.
- (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 .2203 are applicable to this review. The application is conforming to all applicable criteria, as discussed below.

10A 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 Albemarle 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 19-22, and in Section Q, Form C, the applicant projects that BMA Albemarle will serve 89.8 in-center patients on 29 stations, or a rate of 3.09 patients per station per week or 77.25% utilization rate ($89.8 / 29 = 3.09 / 4 = 0.7725$ or 77.25%), as of the end of the first operating year (CY2022) following project completion. This exceeds the minimum performance standard of 2.8 patients per station per week.
- (c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.

- C- In Section C, pages 19-22, and in Section Q, Form C, pages 66-69, the applicant provides the assumptions and methodology it used to project utilization of the facility.