

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: October 12, 2020

Findings Date: October 12, 2020

Project Analyst: Ena Lightbourne

Team Leader: Fatimah Wilson

Project ID #: E-11938-20

Facility: BMA of Burke County

FID #: 150154

County: Burke

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

Project: Add no more than 5 dialysis stations pursuant to Condition 2 of the facility need for a total of no more than 41 stations upon project 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. (the applicant) proposes to add no more than five dialysis stations to the existing facility (BMA of Burke County) pursuant to Condition 2 of the facility need for a total of no more than 41 stations upon project completion.

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 Burke 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 of Burke County on page 152 of the 2020 SMFP is 77.78 percent or 3.11 patients per station per week, based on 112 in-center dialysis patients and 36 certified dialysis stations (112 patients / 36 stations = 3.11; $3.11 / 4 = 77.78\%$).

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

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

Policies

There is one policy in the 2020 SMFP 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, pages 14-16; Section N, page 54; Section O, pages 56-59; and referenced exhibits. The information provided by the applicant is reasonable and 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 15-16; Section C, pages 26-27; Section L, pages 48-51; Section N, pages 54-55; and referenced exhibits. The information provided by the applicant is reasonable and 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 33-36; Section N, page 54; 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 quality, equitable access, and maximum 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:

- 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 five dialysis stations to the existing facility (BMA of Burke County) pursuant to Condition 2 of the facility need for a total of no more than 41 stations upon project completion.

Patient Origin

On page 113, the 2020 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 Burke County. Facilities may serve residents of counties not included in their service area.

The following tables illustrate current and projected patient origin for in-center (IC), Home Hemodialysis (HH), and peritoneal dialysis (PD) patients at BMA of Burke County.

BMA of Burke County Current Patient Origin						
County	Last Full Operating Year CY 2019					
	# of IC Patients	% of Total	# of HH Patients	% of Total	# of PD Patients	% of Total
Burke	106	93.8%	2.0	66.7%	9.0	81.8%
Buncombe			1.0	33.3%		
Caldwell	3.0	2.7%			1.0	9.1%
Catawba					1.0	9.1%
Cleveland	1.0	0.9%				
McDowell	3.0	2.7%				
Total	113.0	100.0%	3.0	100.0%	11.0	100.0%

Source: Section C, page 19

BMA of Burke County Projected Patient Origin						
County	Second Full Operating Year CY 2023					
	# of IC Patients	% of Total	# of HH Patients	% of Total	# of PD Patients	% of Total
Burke	117.6	94.4%	5.2	83.9%	10.6	84.1%
Buncombe			1.0	16.1%		
Caldwell	2.0	1.6%			1.0	7.9%
Catawba	1.0	0.8%				
Cleveland	1.0	0.8%				
McDowell	3.0	2.4%			1.0	7.9%
Total	124.6	100.0%	6.2	100.0%	12.6	100.0%

Source: Section C, page 20

In Section C, pages 20-24 and Section Q, Form C, pages 69-73, the applicant provides the assumptions and methodology used to project IC, HH and PD patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 24-25, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On pages 24-25, the applicant states:

“Patients with End Stage Renal Disease require dialysis treatment on a regular and consistent basis in order to maintain life... The NC SMFP recognizes that this patient population requires frequent and regular treatment... Failure to receive dialysis care will ultimately lead to the patient’s demise.

...BMA has identified the population to be served as 124.6 in-center dialysis patients, and 16.5 home dialysis patients, projected to be dialyzing with the facility as of the end of the first Operating Year of the project. The in-center utilization rate is calculated to be 3.03 patients per station; or 75.7% utilization.”

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

- According to the 2020 SMFP, as of December 31, 2018, BMA of Burke County was operating at a rate of 3.11 IC patients per station per week, or 77.78 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 need methodology found in Criterion (1) is incorporated herein by reference.
- The applicant projects a utilization rate of 3.03 in-center patients per station per week dialyzing at BMA of Burke County by the end of the first operating year upon certification of the additional stations which exceeds the performance standard of 2.8 in-center patients per station per week for 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

In Section C, pages 20-21, and Section Q, Form C, pages 69-70, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The applicant proposes to add five dialysis stations to the BMA of Burke County facility for a total of 41 dialysis stations upon completion of the project.
- The applicant begins its projections of the future patient population to be served with the facility census as of June 30, 2020. The applicant states that the following table reflects the facility census and county of residence for the patient dialyzing with BMA of Burke County on June 30, 2020.

BMA of Burke County Census June 30, 2020			
	IC	HH	PD
Burke	116	1	7
Buncombe		1	
Caldwell	2		1
Catawba	1		
Cleveland	1		
McDowell	3		1
Total	123	2	9

Section C, page 20

- The applicant projects the growth of the patient census using the Burke County Five-Year Average Annual Change Rate (AACR) of 2.1%, as published in the 2020 SMFP.
- The applicant assumes that the seven in-center patients residing in Caldwell, Catawba, Cleveland, and McDowell Counties will continue dialysis with the facility. The applicant will carry these patients forward into projections of future patient populations but not project any growth of this segment of patient population. These patients will be added at the appropriate time.
- BMA offers home dialysis training and support for both hemodialysis and peritoneal dialysis. The applicant states that the home patient population in BMA facilities in North Carolina is generally increasing, which is consistent with President Trump’s Executive Order on Advance American Kidney Health.¹ The applicant projects that two patients per year will change from in-center dialysis. These two patients will be subtracted from future in-center patient populations and added to home patient populations. The applicant states that one will choose home hemodialysis and one will choose home peritoneal dialysis.
- The applicant projects that one in-center patient will change to home hemodialysis at some point in the six months between July 1, 2020 and December 31, 2020.
- The applicant projects the first two full operating years of the project will be January 1, 2022–December 31, 2022 (CY2022) and January 1, 2023–December 31, 2023 (CY2023).

In Section C, page 21 and Section Q, Form C, page 70, the applicant provided the calculations used to project in-center utilization, as illustrated in the following table.

¹ <https://www.whitehouse.gov/presidential-actions/executive-order-advancing-american-kidney-health/>

BMA of Burke County	
BMA begins with the Burke County patient population of Burke County as of June 30, 2020.	116
Project the Burke County patient population forward for six months to December 31, 2020, using one half of the Burke County Five-Year AACR.	$116 \times 1.0105 = 117.2$
Subtract the patient projected to change to home hemodialysis.	$117.2 - 1 = 116.2$
Project the Burke County patient population forward for one year to December 31, 2021, using the Burke County Five-Year AACR.	$116.2 \times 1.021 = 118.7$
Subtract the patients projected to change to home dialysis.	$118.7 - 2 = 116.7$
Add the patients residing in other counties. This is the projected starting census for this project.	$116.7 + 7 = 123.7$
Project the Burke County patient population forward for one year to December 31, 2022, using the Burke County Five-year AACR.	$116.7 \times 1.021 = 119.1$
Subtract the patients projected to change to home dialysis.	$119.1 - 2 = 117.1$
Add the patients residing in other areas. This is the projected ending census for this project for Operating Year 1.	$117.1 + 7 = 124.1$
Project the Burke County patient population forward for one year to December 31, 2023, using the Burke County Five-year AACR.	$117.1 \times 1.021 = 119.6$
Subtract the patients projected to change to home dialysis.	$119.6 - 2 = 117.6$
Add the patients residing in other areas. This is the projected ending census for this project for Operating Year 2.	$117.6 + 7 = 124.6$

Projected patients for OY1 and OY2 are rounded to the nearest whole number. Therefore, at the end of OY1 (CY2022) the facility is projected to serve 124 in-center patients and at the end of OY2 (CY2023) the facility is projected to serve 125 in-center patients.

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

- OY1: 3.03 patients per station per week or 76.78% ($124 \text{ patients} / 41 \text{ stations} = 3.0244/4 = 0.7561$ or 75.61%)
- OY2: 3.04 patients per station per week or 78.57% ($125 \text{ patients} / 41 \text{ stations} = 3.0488/4 = 0.7622$ or 76.22%)

The projected utilization of 3.03 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:

- The applicant projects future utilization based on the most recent historical patient census.
- The applicant utilized a projected annual growth rate of 2.1 percent for Burke County patients which reflects the Burke County Five-Year AACR, as published in Table 9C of the 2020 SMFP.
- The applicant conservatively does not project growth for its Caldwell, Catawba,

Cleveland and McDowell County patients.

- 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).

Home Hemodialysis and Peritoneal Dialysis

In Section C, page 22, and Section Q, Form C, pages 71-73, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The applicant begins its projections of the future HH and PD patient population to be served with the facility census as of June 30, 2020. The applicant states that the following table reflects the facility census and county of residence for the patient dialyzing with BMA of Burke County on June 30, 2020.
- The applicant projects the growth of the patient census using the Burke County Five-Year AACR of 2.1%, as published in the 2020 SMFP.

	June 30, 2020		
	IC	HH	PD
Burke	116	1	7
Buncombe		1	
Caldwell	2		1
Catawba	1		
Cleveland	1		
McDowell	3		1
Total	123	2	9

- The applicant assumes that the one home hemodialysis patient residing in Buncombe County and the two peritoneal dialysis patients residing in Caldwell and McDowell Counties will continue dialysis with the facility. The applicant will carry these patients forward into projects of future patient populations but not project any growth of this segment of patient population. These patients will be added at the appropriate time.
- The applicant projects the first two full operating years of the project will be January 1, 2022–December 31, 2022 (CY2022) and January 1, 2023–December 31, 2023 (CY2023).

In Section C, pages 23-24 and Section Q, Form C, pages 72-73, the applicant provided the calculation used to project HH and PD utilization, as illustrated in the following tables.

BMA of Burke County	HH	PD
BMA begins with the Burke County patient population of Burke County as of June 30, 2020.	1	7
Project the Burke County patient population forward for six months to December 31, 2020, using one half of the Burke County Five-Year AACR.	$1 \times 1.0105 = 1.01$	$7 \times 1.0105 = 7.1$
Add the patient projected to change to home hemodialysis.	$1.01 + 1 = 2.01$	
Project the Burke County patient population forward for one year to December 31, 2021, using the Burke County Five-Year AACR.	$2.01 \times 1.021 = 2.05$	$7.1 \times 1.021 = 7.2$
Add the patients projected to change to home dialysis.	$2.05 + 1 = 3.05$	$7.2 + 1 = 8.2$
Add the patients residing in Buncombe County. This is the projected starting census for this project.	$3.05 + 1 = 4.05$	
Add the patients residing in Caldwell and McDowell Counties. This is the projected starting census for this project		$8.2 + 2 = 10.2$
Project the Burke County patient population forward for one year to December 31, 2022, using the Burke County Five-Year AACR.	$3.05 \times 1.021 = 3.1$	$8.2 \times 1.021 = 8.4$
Add the patients projected to change to home dialysis.	$3.1 + 1 = 4.1$	$8.4 + 1 = 9.4$
Add the patients residing in Buncombe County. This is the projected ending census for this project for Operating Year 1.	$4.1 + 1 = 5.1$	
Add the patients residing in Caldwell and McDowell Counties. This is the projected ending census for this project for Operating Year 1.		$9.4 + 2 = 11.4$
Project the Burke County patient population forward for one year to December 31, 2023, using the Burke County Five-Year AACR.	$4.1 \times 1.021 = 4.2$	$8.4 \times 1.021 = 9.6$
Add the patients projected to change to home dialysis.	$4.2 + 1 = 5.2$	$9.6 + 1 = 10.6$
Add the patients residing in Buncombe County. This is the projected ending census for this project for Operating Year 2.	$5.2 + 1 = 6.2$	
Add the patients residing in Caldwell and McDowell Counties. This is the projected ending census for this project for Operating Year 2.		$10.6 + 2 = 12.6$

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

- The applicant projects future utilization based on the most recent historical patient census.
- The applicant utilized a projected annual growth rate of 2.1 percent for Burke County patients which reflects the Burke County Five-Year AACR, as published in Table 9C of the 2020 SMFP.
- The applicant conservatively does not project growth for its Buncombe, Caldwell, and McDowell County patients.

Access to Medically Underserved Groups

In Section C, page 26, the applicant states:

“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 and underserved person.”

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low income persons	38.3%
Racial and ethnic minorities	40.6%
Women	44.4%
Handicapped Persons	18.0%
The elderly	45.1%
Medicare beneficiaries	83.5%
Medicaid recipients	31.6%

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

Conclusion

The Agency reviewed the:

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

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

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

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

C

The applicant proposes to add no more than five dialysis stations to the existing facility (BMA of Burke County) pursuant to Condition 2 of the facility need for a total of no more than 41 stations upon project completion.

In Section E, page 32, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

Not Applying to Expand the Facility-The applicant states that this alternative was unacceptable due to the growth experienced by BMA of Burke County.

Applying for Fewer than Five Stations-The applicant states that this alternative was less effective because of the growth of the patient census at the facility.

On pages 24-25, the applicant demonstrates the need for its proposal based on the projected growth of the patient census at BMA of Burke County.

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

- The application is conforming to all 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. **Bio-Medical Applications of North Carolina, Inc. shall materially comply with all representations made in the certificate of need application.**
 2. **Pursuant to Condition 2 of the facility need determination in the 2020 SMFP, Bio-Medical Applications of North Carolina, Inc. shall develop no more than five additional in-center dialysis stations for a total of no more than 41 in-center (and home hemodialysis) stations at BMA of Burke County upon project completion.**
 3. **Bio-Medical Applications of North Carolina, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to add no more than five dialysis stations to the existing facility (BMA of Burke County) pursuant to Condition 2 of the facility need for a total of no more than 41 stations upon project completion.

Capital and Working Capital Costs

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

BMA of Burke County Capital Costs	
Construction/Renovation Contract(s)	\$200,000
Non-Medical Equipment	\$3,750
Furniture	\$15,000
Total	\$218,750

In Section Q, page 78, the applicant provides the assumptions used to project the capital cost.

In Section F, pages 34-35, the applicant states that there will be no start-up or initial operating expenses associated with the proposed project since it is an operational facility.

Availability of Funds

In Section F.2, page 33, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	Bio-Medical Applications of North Carolina, Inc.	Total
Loans	\$0	\$ 0
Accumulated reserves or OE *	\$218,750	\$218,750
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$218,750	\$218,750

* OE = Owner's Equity

Exhibit F-2 contains a letter, dated August 17, 2020, from the Senior Vice President and Treasurer to 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 letter states that Fresenius Medical Care Holdings, Inc. Consolidated Balance Sheets for year ending December 31, 2019, reflects more than \$446 million in cash equivalents and over \$25 billion in assets to fund the capital cost of the proposed project.

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

Projected Revenues and Operating Expenses		
BMA of Burke County	Operating Year 1 CY 2022	Operating Year 2 CY 2023
Total Treatments	20,612.9	21,014.7
Total Gross Revenues (Charges)	\$129,676,025	\$132,203,697
Total Net Revenue	\$6,316,945	\$6,431,618
Average Net Revenue per Treatment	\$306.45	\$306.05
Total Operating Expenses (Costs)	\$5,551,621	\$5,144,805
Average Operating Expenses per Treatment	\$269.32	\$224.81
Net Income/Profit	\$765,324	\$1,286,813

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

The applicant proposes to add no more than five dialysis stations to the existing facility (BMA of Burke County) pursuant to Condition 2 of the facility need for a total of no more than 41 stations upon project completion.

On page 113, the 2020 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 Burke 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 Burke County as of December 31, 2018. The applicant owns and operates one dialysis facility in Burke County. The applicant is the only provider of dialysis services in Burke County.

Burke County Dialysis Facilities

Facility Name	Certified Stations as of 12/31/2018	# of In-Center Patients as of 12/31/2018	Utilization by Percent as of 12/31/2018	Patients Per Station
BMA of Burke County	36	112	77.78%	3.11
Total	36	112		

Source: 2020 SMFP, Table 9B

In Section G, page 38, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Burke County. The applicant states:

“The projections of future patient populations to be served begins with the current patient population of the facility and an increase of the Burke County patient

population at a rate of 2.1%. The applicant has not projected to serve patients currently served in another facility, or served by another provider. The stations are needed at BMA of Burke County to support the rapidly growing patient census at the facility.”

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

- The applicant’s proposal to add dialysis stations is based on the facility need methodology.
- 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 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.

- (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, 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 08/2020	2nd Full Operating Year CY 2023
Administrator (FMC Clinic Manager)	1.00	1.00
Registered Nurse (RNs)	4.00	5.00
Home Training Nurse	1.00	2.00
Technicians (PCT)	14.00	15.00
Dietician	1.00	1.25
Social Worker	1.00	1.25
Maintenance	1.00	1.00
Administration/Business Office	1.00	1.00
Other: FMC Director Operations	0.20	0.20
Other: In-Service	0.25	0.25
Other: Chief Tech	0.20	0.20
TOTAL	24.65	28.15

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, page 39, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H, page 40, the applicant identifies the current medical director. In Exhibit H-4, the applicant provides a letter from the medical director indicating an interest in continuing to serve as medical director for the proposed services.

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

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 41, the applicant states that the following ancillary and support services are necessary for the proposed services:

BMA of Burke County – Ancillary and Support Services	
Services	Provider
Self-care training Home training HH PD Accessible follow-up program Isolation – hepatitis B Positive Patients Nutritional counseling Social Work services	Provided on site by applicant
Laboratory services	On site blood draw; analysis by Spectra Labs
Vascular surgery	Foothills Access Center, Lenoir, NC
Pediatric nephrology	Referral to Atrium Health-CMC, or Wake Forest Baptist Hospital
Acute dialysis in an acute care setting	Carolina Health Care System Blue Ridge; Frye Regional Medical Center; UNC Caldwell; Catawba Valley Medical Center
Transplantation services	Wake Forest Baptist Hospital; Duke UMC; UNC Hospital
Emergency care	Provided by facility staff until ambulance arrival
Blood bank services	Carolina Health Care System Blue Ridge
X-ray, diagnostic and evaluation services	Carolina Health Care System Blue Ridge
Psychological counseling	Referral to A Caring Alternative
Vocational rehabilitation counseling and services	Referral to Burke Vocational
Transportation	Greenway Transportation; Specialized transportation

On page 41, the applicant adequately explains how each ancillary and support service is or will be made available.

In Section I, page 42, the applicant describes its existing and proposed relationships with other local health care and social service providers.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

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

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

NA

The applicant is not 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 44, the applicant states that the project involves renovating 500 square feet of existing space. Line drawings are provided in Exhibit K-2.

On page 44, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal.

On page 45, 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.

On pages 45-46, 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 49, the applicant provides the historical payor mix during CY 2019 for the proposed services, as shown in the table below.

BMA of Burke County Historical Payor Mix CY 2019						
Payor Source	In-Center Dialysis		HH		PD	
	# of Patients	% of Total Patients	# of Patients	% of Total Patients	# of Patients	% of Total Patients
Self-Pay	2.31	2.04%	0.00	0.00%	0.00	0.00%
Insurance*	13.61	12.05%	0.00	0.00%	1.45	13.14%
Medicare*	75.69	66.99%	2.39	79.53%	9.30	84.55%
Medicaid*	5.50	4.87%	0.61	20.47%	0.19	1.69%
Medicare/Commercial	10.84	9.60%	0.00	0.00%	0.07	0.62%
Other: Misc. Incl. VA	5.04	4.46%	0.00	0.00%	0.00	0.00%
Total	113.00	100.00%	3.00	100.00%	11.00	100.00%

*Including any managed care plans.

In Section L, page 48, the applicant provides the following comparison.

BMA of Burke County	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	44.4%	50.0%
Male	55.6%	50.0%
Unknown		
64 and Younger	54.9%	79.3%
65 and Older	45.1%	20.7%
American Indian	0.0%	0.9%
Asian	15.8%	3.6%
Black or African-American	20.3%	6.9%
Native Hawaiian or Pacific Islander	0.8%	0.7%
White or Caucasian	63.9%	81.4%
Other Race	0.0%	6.5%
Declined / Unavailable	0.0%	

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

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, in Section L, page 49, the applicant states:

“BMA does not have any obligations under any applicable federal regulations to provide uncompensated care, community service, or access by minorities and handicapped persons.”

In Section L, page 50, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 50, 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 of Burke County Projected Payor Mix CY 2023						
	In-Center Dialysis		HH		PD	
Payor Source	# of Patients	% of Total Patients	# of Patients	% of Total Patients	# of Patients	% of Total Patients
Self-Pay	2.50	2.04%	0.00	0.00%	0.00	0.00%
Insurance*	15.00	12.05%	0.00	0.00%	1.65	13.14%
Medicare*	83.40	66.99%	4.93	79.53%	10.65	84.55%
Medicaid*	6.10	4.87%	1.27	20.47%	0.21	1.69%
Medicare/Commercial	12.00	9.60%	0.00	0.00%	0.08	0.62%
Other: Misc. Incl. VA	5.60	4.46%	0.00	0.00%	0.00	0.00%
Total	124.60	100.00%	6.20	100.00%	12.60	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 2.04% of total in-center services will be provided to self-pay patients, 66.99% to Medicare patients and 4.87% to Medicaid patients.

On page 50, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal years of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- The applicant’s projected payor mix is based upon the facility’s recent history of actual treatment volumes of the facility.
- The applicant projects no significant change to the patient payor mix.

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 51, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section M, page 52, 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-2.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to add no more than five dialysis stations to the existing facility (BMA of Burke County) pursuant to Condition 2 of the facility need for a total of no more than 41 stations upon project completion.

On page 113, the 2020 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 Burke 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 Burke County as of December 31, 2018. The applicant owns and operates one dialysis facility in Burke County. The applicant is the only provider of dialysis services in Burke County.

Burke County Dialysis Facilities

Facility Name	Certified Stations as of 12/31/2018	# of In-center Patients as of 12/31/2018	Utilization by Percent as of 12/31/2018	Patients Per Station
BMA of Burke County	36	112	77.78%	3.11
Total	36	112		

Source: 2020 SMFP, Table 9B

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 53, the applicant states:

“The applicant does not project to serve dialysis patients currently being served by another provider.

...

...BMA seeks the opportunity to continue providing dialysis care and treatment to the patients of the area who have expressed their desire to receive dialysis care and treatment at BMA of Burke County.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 54, the applicant states:

“Approval of this application will allow BMA of Burke County 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 54, the applicant states:

“Fresenius Medical Care, parent organization for this facility, expect every facility to provide high quality care to every patient at every treatment.”

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 54, the applicant states:

“It is corporate policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.”

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, pages 62-67, the applicant identifies the kidney treatment centers located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 126 of this type of facility located in North Carolina.

In Section O, page 59, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to immediate jeopardy has not 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 126 facilities, the applicant provided 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 .2200 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 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.*
- NA- The applicant does not propose to establish a new kidney disease treatment center or dialysis facility. Therefore, this performance standard is not applicable to this review.
- (b) *An applicant proposing to increase the number of dialysis stations in:*
(1) *an existing dialysis facility; or*
(2) *a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need;*
shall document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the additional stations.
- C- In Section C, page 21, and Section Q, Form C, page 70, the applicant projects that BMA of Burke County will serve 124 in-center patients on 41 stations, or a rate of 3.03 patients per station per week, as of the end of the first operating year following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- (c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section C, pages 20-24, and Section Q, Form C, pages 69-73 the applicant provides the assumptions and methodology it uses to project utilization of the facility. The

discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.