

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: January 10, 2019

Findings Date: January 10, 2019

Project Analyst: Tanya M. Saporito

Team Leader: Gloria C. Hale

Project ID #: E-11774-19

Facility: BMA Lenoir

FID #: 170328

County: Caldwell

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

Project: Add no more than 1 dialysis station for a total of no more than 43 stations upon completion of this project and the following four projects: E-11377-17 (relocate facility); E-11401-17 (add 7 stations); E-11528-18 (change of scope); and E-11569-18 (add 1 station)

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. (hereinafter referred to as “the applicant” or BMA) proposes to add one dialysis station to BMA Lenoir, an existing dialysis facility, for a total of 43 dialysis stations upon completion of this project and four pending projects [E-11377-17 (relocate facility); E-11401-17 (add 7 stations); E-11528-18 (change of scope); and E-11569-18 (add 1 station)].

Need Determination

The 2019 State Medical Facilities Plan (2019 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table D, page 62, in the July 2019 Semiannual Dialysis Report (SDR), the county need

methodology shows there is a deficit of four dialysis stations in Caldwell County, but because there are facilities with a reported utilization of less than 80% in Table B of the 2019 SDR and the deficit is less than 10 stations, there is no county need determination for new dialysis stations for Caldwell County.

However, the applicant is eligible to apply for additional dialysis stations in an existing facility based on the facility need methodology if the utilization rate for that dialysis facility, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. The utilization rate reported for BMA Lenoir in the July 2019 SDR is 3.65 patients per station per week, or 91.2%, based on 124 in-center dialysis patients and 34 certified dialysis stations [$124 / 34 = 3.647$; $3.647 / 4 = 0.9118$]. Therefore, BMA Lenoir is eligible to apply for additional stations based on the facility need methodology.

Application of the facility need methodology indicates that one station is needed at this facility, as illustrated in the following the table:

BMA LENOIR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/18		91.2%
Certified Stations		34
Pending Stations		8
Total Existing and Pending Stations		42
In-Center Patients as of 12/31/18 (July 2019 SDR) (SDR2)		124
In-Center Patients as of 6/30/18 (Jan 2019 SDR) (SDR1)		117
Step	Description	Result
	Difference (SDR2 - SDR1)	7
(i)	Multiply the difference by 2 for the projected net in-center change	14
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/18	0.1197
	(ii) Divide the result of Step (i) by 12	0.0100
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/17 until 12/31/18)	0.1197
(iv)	Multiply the result of Step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	138.8376
(v)	Divide the result of Step (iv) by 3.2 patients per station	43.3868
	and subtract the number of certified and pending stations to determine the number of stations needed	1.3868

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed at BMA Lenoir is one. Step (C) of the facility need methodology states, “*The facility may apply to expand to meet the need established ..., up to a maximum of ten stations.*” The applicant proposes to add one new station; therefore, the application is consistent with the facility need determination for dialysis stations.

Policies

Policy GEN-3: Basic Principles is the only Policy in the 2019 SMFP which is applicable to this review.

Policy GEN-3, on page 31 of the 2019 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.3 (a and d), pages 12 and 14, respectively; Sections N.1 and N.2(b), pages 52 - 53; Section O, pages 55 - 58; 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.3, pages 12 - 13; Section L, pages 49 – 50; Section N.2(c), page 53; 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.3, pages 13 - 14; Section K, pages 43 – 44; Section N.2(a), pages 52 - 53; and referenced exhibits. The information provided by the applicant with regard to its efforts to maximize healthcare value 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, and
- information publicly available during the review and used by the Agency.

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

- (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 one dialysis stations to BMA Lenoir for a total of 43 dialysis stations upon completion of this project and the following four projects:

1. Project ID #E-11377-17: Relocate the facility and 20 dialysis stations.
2. Project ID #E-11401-17: Add seven stations to BMA Lenoir for a total of 27.
3. Project ID #E-11528-18: Change of scope application to merge Project ID # E-11376-17 and Project ID #E-11377-17. BMA Lenoir would now be a 41-station facility [$14 + 20 + 7 = 41$].
4. Project ID #E-11569-18: Add one station to BMA Lenoir for a total of 42 stations.

Patient Origin

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area for this facility is Caldwell County. Facilities may serve residents of counties not included in their service area.

In Section C.2, page 17, the applicant provides the historical patient origin for BMA Lenoir in-center (IC), home hemodialysis (HHD) and peritoneal dialysis (PD) patients as of December 31, 2018, as illustrated in the table below:

**BMA Lenoir Historical Patient Origin
 January 1, 2018 – December 31, 2018**

COUNTY	# IN-CENTER Pts.	% OF TOTAL	# HHD Pts.	% OF TOTAL	# PD Pts.	% OF TOTAL
Caldwell	120	96.77%	1	50.00%	9	90.00%
Alexander	1	0.81%	0	0.00%	0	0.00%
Burke	1	0.81%	1	50.00%	0	0.00%
Wilkes	0	0.00%	0	0.00%	1	10.00%
Other States	2	1.61%	0	0.00%	0	0.00%
Total	124	100.0%	2	100.0%	10	100.0%

Totals may not sum due to rounding

The applicant projects patient origin for the second full year of operation, calendar year (CY) 2022 in Section C, page 17, as illustrated in the following table:

**BMA Lenoir Projected Patient Origin
 January 1, 2022– December 31, 2022**

COUNTY	# IN-CENTER Pts.	% OF TOTAL	# HHD Pts.	% OF TOTAL	# PD Pts.	% OF TOTAL
Caldwell	173.0	100.0%	1.36	100.00%	12.3	86.00%
Wilkes	0	0.00%	0	0.00%	2.0	14.00%
Total	173.0	100.0%	1.36	100.0%	14.3	100.0%

Totals may not sum due to rounding

In Section C, pages 18 - 20, the applicant provides the assumptions and methodology it used to project patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.4, page 21 the applicant states that the need the proposed population has for the proposed services is a function of the individual patient need for dialysis care and treatment, stating that dialysis treatment is necessary for patients with End Stage Renal Disease.

In-Center Need

In Section C, page 18 and Section Q, pages 67, the applicant provides the assumptions and methodology for projecting in-center patient utilization, summarized as follows:

- The applicant provides a table on pages 18 and 67 that shows the facility in-center census as of December 31, 2018 and June 30, 2019, as summarized below.

**BMA LENOIR
 IN-CENTER PATIENTS**

COUNTY	12/31/2018	6/30/2019
Caldwell	120	127
Alexander	1	0
Burke	1	0
Other States	2	0
Total	124	127

- The applicant states that it will begin its analysis with the BMA Lenoir patient census as of June 30, 2019, which was submitted to the Agency on the ESRD Data Collection form in August 2019 and is shown in the table above.
- The applicant projects growth of the Caldwell County patient population based on the 9.2% Caldwell County Five Year Average Annual Change Rate (AACR) published in the July 2019 SDR.
- The applicant projects project completion by December 31, 2020. Therefore, Operating Year (OY) 1 is calendar year (CY) 2021, January 1 - December 31, 2021 and OY 2 is CY 2022, January 1 - December 31, 2022.

Projected Utilization

In Section C, page 18 and Section Q, page 67, the applicant provides the methodology it used to project utilization, based on its stated assumptions, as illustrated in the following table:

BMA LENOIR IN-CENTER PATIENTS	
Begin with Caldwell County patient population as of June 30, 2019.	127
Project forward six months to December 31, 2019 using one-half of the Caldwell County Five Year AACR of 9.2% in the July 2019 SDR.	$127 \times 1.046 = 132.8$
Project forward one year to December 31, 2020 using Caldwell County Five Year AACR.	$132.8 \times 1.092 = 145.1$
Project forward one year to December 31, 2021, using Caldwell County Five Year AACR.	$145.1 \times 1.092 = 158.4$
Project forward one year to December 31, 2022, using Caldwell County Five Year AACR.	$158.4 \times 1.092 = 173.0$

Source: Tables in Sections C and Q, pages 18 and 67, respectively.

At the end of OY 1 (CY 2021), BMA Lenoir projects to serve 158 in-center patients on 43 stations, for a utilization rate of 91.8%; and at the end of OY 2 (CY 2022) the facility is projected to serve 173 in-center patients on 43 stations, for a utilization rate of 100.0%.

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

- OY 1: 3.67 patients per station per week, or 91.8% utilization: $158 / 43 = 3.67$; $3.67 / 4 = 0.918$.

- OY 2: 4.02 patients per station per week, or 100.5% utilization: 173 patients / 43 stations = 4.02; 4.02 / 4 = 1.005.

The projected utilization of 3.67 patients per station per week at the end of OY 1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

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

- BMA Lenoir was operating at 91.18% capacity as of December 31, 2018, as reported in the July 2019 SDR.
- The applicant projects future patient utilization based on historical utilization.
- The applicant projects growth of the in-center patient population using the Caldwell County Five Year AACR of 9.2%.
- Projected utilization at the end of OY 1 exceeds the minimum of 3.2 patients per station per week required by 10A NCAC 14C .2203(b).

Home Hemo Dialysis and Peritoneal Dialysis

In Section C, pages 19 - 20 and Section Q, pages 68 - 69, the applicant provides the assumptions and methodology for projecting HHD and PD patient utilization, summarized as follows:

- The applicant provides a table on pages 19 and 68 that shows the facility HHD and PD patient census as of December 31, 2018 and June 30, 2019, as summarized below.

**BMA LENOIR
HHD AND PD PATIENTS**

COUNTY	12/31/2018		6/30/2019	
	HHD	PD	HHD	PD
Caldwell	1	9	1	9
Burke	1	0	0	0
Wilkes	0	1	0	2
Total	2	10	1	11

- The applicant states that it will begin HHD and PD utilization with the BMA Lenoir HHD and PD patient census as of June 30, 2019, which was submitted to the Agency on the ESRD Data Collection form in August 2019 and is shown in the table above.
- The applicant projects growth of the patient population based on the 9.2% Caldwell County Five Year Average Annual Change Rate (AACR) published in the July 2019 SDR.

- The applicant states the patients from Wilkes County are dialyzing at BMA Lenoir by choice; therefore, the applicant states it will add the Wilkes County patients to the projected patient census at appropriate points in time.
- The applicant projects project completion by December 31, 2020. Therefore, Operating Year (OY) 1 is calendar year (CY) 2021, January 1 - December 31, 2021 and OY 2 is CY 2022, January 1 - December 31, 2022.

HHD and PD Patient Projected Utilization

In Section C, page 20 and Section Q, page 69, the applicant provides the methodology it used to project utilization, based on its stated assumptions, as illustrated in the following table:

BMA LENOIR HHD AND PD PATIENTS		
	HHD	PD
Begin with the Caldwell County patient population as of June 30, 2019.	1	9
Project Caldwell County population forward six months to December 31, 2019, using one-half of Caldwell County Five Year AACR of 9.2%.	$1 \times 1.046 = 1.046$	$9 \times 1.046 = 9.41$
Project Caldwell County population forward one year to December 31, 2020, using Caldwell County Five Year AACR.	$1.046 \times 1.092 = 1.14$	$9.4 \times 1.092 = 10.28$
Add the Wilkes County patients. This is the projected beginning census.	$1.14 + 0 = 1.14$	$10.28 + 2 = 12.28$
Project Caldwell County population forward one year to December 31, 2020, using Caldwell County Five Year AACR.	$1.14 \times 1.092 = 1.25$	$10.28 \times 1.092 = 11.23$
Add the Wilkes County patients. This is the projected ending census for OY one.	$1.25 + 0 = 1.25$	$11.23 + 2 = 13.23$
Project Caldwell County population forward one year to December 31, 2020, using Caldwell County Five Year AACR.	$1.25 \times 1.092 = 1.36$	$11.23 \times 1.092 = 12.26$
Add the Wilkes County patients. This is the projected ending census for OY two.	$1.36 + 0 = 1.36$	$12.26 + 2 = 14.26$

Source: Tables in Sections C and Q, pages 20 and 69, respectively.

At the end of OY 1 (CY 2021) BMA Lenoir projects to serve 1.25 HHD patients and 13.23 PD patients; and at the end of OY 2 (CY 2022) BMA Lenoir projects to serve 1.36 HHD patients and 14.26 PD patients.

Projected utilization of the home training program is reasonable and adequately supported for the following reasons:

- The applicant projects HHD and PD patients based on its historical utilization.
- The applicant projects growth in the Caldwell County patient population using the 9.2% Caldwell County Five Year AACR, as published in the July 2019 SDR.
- The applicant does not project growth for patients residing outside of Caldwell County but accounts for them in its projections.
- The applicant adequately demonstrates the need for home training services in Caldwell County.

Projected utilization of the total proposed IC, HH, and PD program at BMA Lenoir is reasonable and adequately supported for the reasons stated above.

Access

In Section C.7, pages 22 - 23, the applicant states:

“... 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.

...

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 49, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as summarized in the following table.

**BMA LENOIR
 PROJECTED PAYOR MIX CY 2022**

PAYOR SOURCE	IN-CENTER		HOME HEMODIALYSIS		PERITONEAL DIALYSIS	
	# OF PATIENTS	% OF TOTAL	# OF PATIENTS	% OF TOTAL	# OF PATIENTS	% OF TOTAL
Self-pay	3.72	2.15%	0.00	0.00%	0.00	0.00%
Insurance*	11.24	6.50%	0.00	0.00%	0.37	2.59%
Medicare*	107.36	62.06%	0.56	40.89%	10.52	73.81%
Medicaid*	7.11	4.11%	0.00	0.00%	0.24	1.72%
Medicare/Commercial	32.68	18.89%	0.81	59.11%	1.56	10.96%
Miscellaneous (Incl. VA)	10.88	6.29%	0.00	0.00%	1.56	10.92%
Total	172.98	100.00%	1.36	100.00%	14.26	100.00%

Totals may not sum due to rounding

*Includes any managed care plans

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

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

NA

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

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

CA

The applicant proposes to add one dialysis station to BMA Lenoir for a total of 43 dialysis stations upon completion of this project and four other projects.

In Section E, page 28, the applicant states it considered the following alternative related to serving the needs of the dialysis patients in the service area:

1. Maintain the status quo – the applicant states this was not a reasonable alternative because BMA Lenoir is the only facility in Caldwell County. There is no facility from which to relocate stations. The applicant states the only alternative was to apply or not to apply.

On page 28, the applicant states that it elected to add one station pursuant to the facility need methodology because this proposal is the most cost-effective approach to providing the necessary services for the patient population projected to be served at BMA Lenoir.

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

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

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. 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 the facility need determination in the July 2019 SDR, Bio-Medical Applications of North Carolina, Inc. shall develop no more than one additional dialysis station at BMA Lenoir for a total of no more than 43 dialysis stations, which shall include any home hemodialysis training or isolation stations, upon completion of this project and Project ID #E-11377-17 (relocate facility); Project ID #E-11401-17 (add 7 stations); Project ID #E-11528-18 (change of scope); and Project ID #E-11569-18 (add 1 station).**
 - 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 one dialysis station to BMA Lenoir for a total of 43 dialysis stations upon completion of this project and four other projects.

Capital and Working Capital Costs

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

Non-Medical Equipment	\$750
Furniture	\$3,000
Total	\$3,750

In Section Q, the applicant provides the assumptions used to project the capital cost. In the Form F.1a in Section Q, the applicant provides information with regard to capital expenditures for the pending projects associated with this project. However, the only capital cost that is reviewable as part of this application is the cost associated with the addition of one dialysis station as proposed in this application.

In Section F.3, pages 30 and 31, the applicant states there will be no start-up or initial operating expenses associated with the proposed project since this is an existing facility that is already operational.

Availability of Funds

In Section F.2, page 29, the applicant states that the capital cost will be funded as shown in the table below.

SOURCES OF CAPITAL COST FINANCING

TYPE	BIO-MEDICAL APPLICATIONS OF NORTH CAROLINA, INC.	TOTAL
Loans	0	0
Accumulated reserves or OE *	\$3,750	\$3,750
Bonds	0	0
Other (Specify)	0	0
Total Financing	\$3,750	\$3,750

* OE = Owner's Equity

Exhibit F-2 contains a letter dated September 16, 2019 from the Senior Vice President and Treasurer, authorizing and committing accumulated reserves of Fresenius Medical Care Holdings, Inc. (FMCH), the parent company for BMA, for the capital costs of the project. The letter also documents that the 2018 Consolidated Balance Sheet for FMCH reflects more than \$1.8 billion in cash, and total assets exceeding \$20 billion.

Financial Feasibility

The applicant provides pro forma financial statements for the first two full operating years 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 summarized in the table below.

BMA LENOIR PROJECTED REVENUE AND OPERATING EXPENSES

	OY 1 CY 2021	OY 2 CY 2022
Total Treatments (IC, HH and PD)	24,521.25	26,749.97
Total Gross Revenue (charges)	\$154,263,192	\$168,284,089
Total Net Revenue	\$7,086,858	\$7,732,111
Average Net Revenue per Treatment	\$289.01	\$289.05
Total Operating Expenses (costs)	\$5,909,673	\$6,214,725
Average Operating Expense per Treatment	\$241.00	\$232.33
Net Income / Profit (loss)	\$1,177,185	\$1,517,386

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, and
- exhibits to the application.

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
 - The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the proposal.
 - The applicant adequately demonstrates the availability of 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 one dialysis station to BMA Lenoir for a total of 43 dialysis stations upon completion of this project and four other projects.

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning*

Area, each of the 94 remaining counties is a separate dialysis station planning area.” The facility is located in Caldwell County; thus, the service area for this facility consists of Caldwell County. Facilities may also serve residents of counties not included in their service area.

According to the July 2019 SDR, BMA is the only provider of dialysis services in Caldwell County. The applicant was approved to relocate the existing facility in Project ID #E-11377-17, but BMA is the only dialysis provider in the county.

Per the July 2019 SDR, as of December 31, 2018, BMA Lenoir was operating at 91.18%, with 124 in-center patients on 34 stations.

The applicant provides the same data as above in Section G, page 34, and also provides the updated data for BMA Lenoir as submitted on the ESRD Data Collection Forms in August 2019. That data shows an increase in the number of patients to 127, for a utilization rate of 93.38% [$127 / 34 = 3.753$; $3.753 / 4 = 0.9338$].

In Section G, page 34 - 35, the applicant explains why it believes the proposal would not result in the unnecessary duplication of existing or approved dialysis services in Caldwell County based on the utilization as of June 30, 2019. The applicant states:

“This is an application to add one dialysis stations to BMA Lenoir. BMA Lenoir is the only facility in Caldwell County. The July 2019 SDR reports that Caldwell County has a deficit of four stations. Approval of this application not cause [sic] duplication of services, but will ensure an adequate inventory of dialysis stations exists fo [sic] the ESRD patient populatoin [sic] of the county.”

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 for one additional dialysis station at BMA Lenoir, as calculated using the methodology in the July 2019 SDR.
- The applicant does not propose to develop more dialysis stations than are shown to be needed in the service area.
- The applicant adequately demonstrates that the proposed dialysis stations are needed in addition to the existing or approved additional dialysis stations.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

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

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

C

In Form H Staffing, in Section Q, page 84, the applicant provides a table illustrating current and projected OY 2 staffing in full time equivalents (FTEs) for BMA Lenoir, as summarized below.

BMA LENOIR CURRENT AND PROJECTED STAFFING

POSITION	FTE POSITIONS AS OF 6/30/19	FTE POSITIONS OY1	FTE POSITIONS OY2
FMC Clinic Manager	1.00	1.00	1.00
RN	6.50	6.50	6.50
Home Training Nurse	3.00	3.00	3.00
Patient Care Technician	15.00	15.00	15.00
Dietician	1.50	1.50	1.50
Social Worker	1.50	1.50	1.50
Equipment Technician	1.00	1.00	1.00
Administration	1.75	1.75	1.75
FMC Director Operations	0.15	0.15	0.15
In-Service	0.20	0.20	0.20
Chief Technician	0.20	0.20	0.20
Total	31.80	31.80	31.80

Source: Section Q Form H

The applicant does not project to hire any new FTE positions as a result of this project. The assumptions and methodology used to project existing 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 Operating Costs. In Section H, page 36, the applicant describes the methods used to recruit or fill new positions if necessary and its existing training and continuing education programs. Exhibit H contains documentation of its continuing education programs. In Section H.4, page 37, the applicant identifies the current medical director for the facility as Dr. Robert Qualheim. In Exhibit H-4, the applicant provides a letter from Dr. Qualheim confirming his intent to continue 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, and
- exhibits to the application.

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

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

C

In Section I, page 40, the applicant states that the following ancillary and support services are necessary for the proposed services, and explains how each ancillary and support service is made available:

BMA LENOIR ANCILLARY AND SUPPORT SERVICES	
SERVICES	PROVIDER
Self-care training	On Site by Applicant
Home training Home Hemodialysis Peritoneal Dialysis Accessible follow-up program	On Site by Applicant
Psychological counseling	Vaya Health, Cornerstone Counseling
Isolation – hepatitis	On Site by Applicant
Nutritional counseling	On Site by Applicant
Social Work services	On Site by Applicant
Acute dialysis in an acute care setting	Caldwell UNC Health Care or Frye Regional Medical Center
Emergency care	Caldwell UNC Health Care or Frye Regional Medical Center
Blood bank services	Caldwell UNC Health Care or Frye Regional Medical Center
Diagnostic and evaluation services	Caldwell UNC Health Care or Frye Regional Medical Center
X-ray services	Caldwell UNC Health Care or Frye Regional Medical Center
Laboratory services	On Site by Applicant
Pediatric nephrology	Referral to Wake Forest Baptist Hospital or UNC
Vascular surgery	Dr. Randall Bast, Foothills Dialysis Access Center Lenoir
Transplantation services	Referral to Wake Forest Baptist Hospital or UNC
Vocational rehabilitation & Counseling	Vocational Rehabilitation in Morganton
Transportation	Greenway, Blue Ridge Transportation

Source: Application page 40

In Section I, page 40, the applicant describes its existing and proposed relationships with other local health care and social service providers. In Exhibit I, the applicant provides supporting documentation for established relationships with local health care providers and for referrals.

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

Conclusion

The Agency reviewed the:

- application, and
- 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.

NA

The applicant proposes to add one dialysis stations to BMA Lenoir for a total of 43 dialysis stations upon project completion.

In Section K, page 43, the applicant states that the proposed project will involve renovation of 90 square feet.

The applicant does not propose to

- construct any new space
- make more than minor renovations to any existing space

Therefore, Criterion (12) is not applicable to this review.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and 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 48, the applicant provides the historical payor mix during CY 2018 for its existing services at BMA Lenoir, as summarized in the table below.

**BMA LENOIR
 HISTORICAL PAYOR MIX CY 2018**

Payor Source	In-Center Patients		HHD PATIENTS		PD Patients	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	2.66	2.15%	0.00	0.00%	0.00	0.00%
Insurance*	80.6	6.50%	0.00	0.00%	0.26	2.59%
Medicare*	76.96	62.06%	0.82	40.89%	7.38	73.81%
Medicaid*	5.09	4.11%	0.00	0.00%	0.17	1.72%
Medicare/Commercial	23.43	18.89%	1.18	59.11%	1.10	10.96%
Miscellaneous (Incl. VA)	7.80	6.29%	0.00	0.00%	1.09	10.92%
Total	124.00	100.00%	2.00	100.00%	10.00	100.00%

Totals may not sum due to rounding

*Including any managed care plans

In Section L.1(a), page 47, the applicant compares demographical information on BMA Lenoir patients and the service area patients during CY 2018, as summarized below:

	PERCENTAGE OF TOTAL BMA LENOIR PATIENTS SERVED DURING THE LAST FULL OY	PERCENTAGE OF THE POPULATION OF THE SERVICE AREA
Female	43.7%	50.5%
Male	56.3%	49.5%
Unknown		
64 and Younger	68.9%	80.1%
65 and Older	31.1%	19.9%
American Indian	0.0	0.6%
Asian	0.0%	0.7%
Black or African-American	23.0%	5.0%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	73.3%	87.1%
Other Race	3.7%	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>. Just enter in the name of the county.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the 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, page 48, that it has no obligation in any of its facilities to provide uncompensated care or community service under any federal regulations.

In Section L, page 49, 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, and
- 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 49, the applicant projects the following payor mix for the proposed services during the second full operating year following completion of the project, as summarized in the table below.

**BMA LENOIR
 PROJECTED PAYOR MIX CY 2022**

Payor Source	In-Center Patients		HHD PATIENTS		PD Patients	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	3.72	2.15%	0.00	0.00%	0.00	0.00%
Insurance*	11.24	6.50%	0.00	0.00%	0.37	2.59%
Medicare*	107.36	62.06%	0.56	40.89%	10.52	73.81%
Medicaid*	7.11	4.11%	0.00	0.00%	0.24	1.72%
Medicare/Commercial	32.68	18.89%	0.81	59.11%	1.56	10.96%
Miscellaneous (Incl. VA)	10.88	6.29%	0.00	0.00%	1.56	10.92%
Total	172.98	100.00%	1.36	100.00%	14.26	100.00%

Totals may not sum due to rounding

*Including any managed care plans

As shown in the table above, during the second year of operation, the applicant projects that 2.15% of in-center services will be provided to self-pay patients, 80.95% to Medicare patients (includes Medicare and Medicare/Commercial), and 4.11% to Medicaid patients.

On pages 49 - 50, the applicant provides the assumptions and methodology it uses to project payor mix during the second full year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because the projected payor mix is based on the historical payor mix of BMA Lenoir.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

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

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

C

In Section L, page 50, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion

The Agency reviewed the:

- application, and
- 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 51, 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.

Conclusion

The Agency reviewed the:

- application, and
- 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 one dialysis station to BMA Lenoir for a total of 43 dialysis stations upon completion of this project and four other projects.

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” The facility is located in Caldwell County; thus, the service area for this facility consists of Caldwell County. Facilities may also serve residents of counties not included in their service area.

According to the July 2019 SDR, BMA is the only provider of dialysis services in Caldwell County. The applicant was approved to relocate the existing facility in Project ID #E-11377-17, but BMA is the only dialysis provider in the county.

Per the July 2019 SDR, as of December 31, 2018, BMA Lenoir was operating at 91.18%, with 124 in-center patients on 34 stations.

The applicant provides the same data as above in Section G, page 34, and also provides the updated data for June 2019 for BMA Lenoir as submitted on the ESRD Data Collection Forms in August 2019. That data shows an increase in the number of patients to 127, for a utilization rate of 93.38% [$127 / 34 = 3.753$; $3.753 / 4 = 0.9338$].

In Section N, pages 52 - 53, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality, and access to the proposed services. The applicant states:

“The applicant does not expect this proposal to have any effect on the competitive climate in Caldwell County. The applicant does not project to serve dialysis patients currently being served by another provider. The projected patient population for the BMA Lenoir facility begins with current patient population.

There is currently one dialysis facility in Caldwell County: BMA Lenoir. With this application, BMA seeks the opportunity to continue providing dialysis care and treatment to the patients of the area... .

...

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

...

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

...

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

...

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.”

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

- The cost-effectiveness of the proposal (see Sections B, F, and Q of the application and any exhibits).
- Quality services will be provided (see Sections B and O of the application and any exhibits).
- Access will be provided to underserved groups (see Sections B and L of the application and any exhibits).

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

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

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In 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 127 dialysis facilities owned, operated, or managed by the applicant or a related entity located in North Carolina.

In Section O, page 58, 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 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 .2200 are applicable to this review. The application is conforming to all applicable criteria, as discussed below.

10 NCAC 14C .2203 PERFORMANCE STANDARDS

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

-NA- BMA Lenoir is an existing facility.

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

-C- In Section C, page 18 and Section Q Form C, page 66, the applicant projects BMA Lenoir will serve 158.4 in-center patients on 43 stations, or a rate of 3.6 patients per station per week, as of the end of the first operating year following project completion. This exceeds the minimum performance standard of 3.2 patient per station per week. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

- C- In Section C, pages 18 - 20 and Section Q, pages 67 - 69, the applicant provides the assumptions and methodology it used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.