

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: Ena Lightbourne

Team Leader: Fatimah Wilson

Project ID #: E-11569-18

Facility: BMA Lenoir

FID #: 170328

County: Caldwell

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

Project: Add one station for a total of 42 stations upon completion of this project, and the following projects: Project ID # E-11528-18 (Change of Scope); Project ID # E-11401-17 (add seven stations); and Project ID# E-11377-17 (relocate BMA Lenoir)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a BMA Lenoir proposes to add one dialysis station to the existing facility for a total of 42 stations upon completion of this project, and the following projects: Project ID # E-11528-18 (Change of Scope); Project ID # E-11401-17 (add seven stations); and Project ID# E-11377-17 (relocate BMA Lenoir).

Need Determination

The 2018 State Medical Facilities Plan (2018 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2018 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of three dialysis stations in Caldwell County. Therefore, the July 2018 SDR does not indicate a need for additional stations in Caldwell County based on the county need

methodology, which states that the county deficit must be 10 or greater to establish a need for additional stations. However, the applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80 percent. The utilization rate reported for BMA Lenoir in the July 2018 SDR is 3.58 patients per station per week, or 89.71 percent, based on 122 in-center dialysis patients and 34 certified dialysis stations [$122 / 34 = 3.58$; $3.58 / 4 = 0.89705$ or 89.71%].

Below is a table that illustrates the facility need for additional dialysis stations at BMA Lenoir:

October 1 Review-JULY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/17		89.71%
Certified Stations		34
Pending Stations		7
Total Existing and Pending Stations		41
In-Center Patients as of 12/31/17 (July 2018 SDR) (SDR2)		122
In-Center Patients as of 6/30/17 (January 2018 SDR) (SDR1)		116
Step	Description	Result
	Difference (SDR2 - SDR1)	6
(i)	Multiply the difference by 2 for the projected net in-center change	12
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/17	0.1034
	(ii) Divide the result of Step (i) by 12	0.0086
(iii)	Multiply the result of Step (ii) by 12	0.1032
(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	134.5904
(v)	Divide the result of Step (iv) by 3.2 patients per station	42.0594
	and subtract the number of certified and pending stations to determine the number of stations needed	1.0595 1

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is one station. 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

There is one policy in the 2018 SMFP which is applicable to this review. Policy GEN-3: Basic Principles, on page 33 of the 2018 SMFP, is applicable to this review because the facility need methodology is applicable to this review. Policy GEN-3 states:

“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical

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

Promote Safety and Quality

The applicant describes how it believes the proposed project would promote safety and quality in Section B.4(a and d), pages 9 and 11-12; Section K.1(g), page 45; Section N.1, page 55; 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 would promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project would promote equitable access in Section B.4(b and d), pages 9-12; Section C.3, pages 18-19; Section L, pages 49-53; Section N.1, page 55, and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project would maximize healthcare value in Section B.4(c and d), pages 10-12; Section C, pages 14-17; Section F, pages 26-33; Section K, pages 43-45; Section N.1, page 55, 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 would 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 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 station to the existing facility for a total of 42 stations upon completion of this project, and the following projects: Project ID # E-11528-18 (Change of Scope); Project ID # E-11401-17 (add seven stations); and Project ID# E-11377-17 (relocate BMA Lenoir).

Patient Origin

On page 365, the 2018 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 is Caldwell. Facilities may serve residents of counties not included in their service area.

In Section C.8, page 21, the applicant provides a table showing the historical patient origin for in-center (IC), home peritoneal dialysis (PD), and home hemodialysis (HHD) patients served by BMA Lenoir, as shown below.

BMA Lenoir Patients by County – 6/30/2017			
County	# of IC Patients	# of HHD Patients	# of PD Patients
Caldwell	107	1	8
Alexander	1	0	0
Burke	4	1	0
Catawba	4	0	0
Wilkes	1	0	1
Total	117	2	9

In Section C.1, page 14, the applicant provides the projected patient origin for BMA Lenoir for IC patients, PD patients, and HHD patients for the first two operating years (OY) following completion of the project, as shown in the table below.

BMA Lenoir Patients by County – Operating Years 1 & 2								
County	Operating Year 1 CY 2020			Operating Year 2 CY 2021			County Patients as % of Total	
	IC	HHD	PD	IC	HHD	PD	OY 1	OY 2
Caldwell	133.2	1.24	10.0	145.3	1.36	10.9	92.3%	92.9%
Alexander	1	0	0	1	0	0	0.6%	0.6%
Burke	4	1	0	4	1	0	3.2%	3.0%
Catawba	4	0	0	4	0	0	2.6%	2.4%
Wilkes	1	0	1	1	0	1	1.3%	1.2%
Total*	143	2	11	155	2	11	100.0%	100.0%

Note: Tables may not foot due to rounding.
 *Rounded down to the whole patient.

The applicant provides the assumptions and methodology used to project patient origin on pages 15-18. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section B.2, pages 6-8, the applicant states that the application is filed pursuant to the facility need methodology in the 2018 SMFP, utilizing the data from the July 2018 SDR. The applicant proposes to add one dialysis station to the existing BMA Lenoir facility, for a total of 42 dialysis stations upon project completion and the following projects: Project ID # E-11528-18 (Change of Scope); Project ID # E-11401-17 (add seven stations); and Project ID# E-11377-17 (relocate BMA Lenoir). In Section C, page 18, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On pages 15-18, the applicant describes its need methodology and assumptions for projecting utilization of the proposed facility as follows:

- The applicant begins the projections by using the in-center, PD and HHD patient census in Caldwell County as of June 30, 2018.
- The applicant assumes that by combining the FKC Caldwell facility with the BMA Lenoir facility, BMA Lenoir will continue to serve patients of Caldwell County and those who choose to dialyze at BMA Lenoir from other counties.
- The applicant assumes that the in-center patient population currently receiving treatment at BMA Lenoir and who currently reside in Caldwell County, will increase at a rate of 9.1 percent, which is the Five Year Average Annual Change Rate (AACR) for Caldwell County published in the July 2018 SDR.
- The applicant is not projecting any increase in patients residing outside of Caldwell County, but will add the patients at appropriate points in time.
- The project is scheduled for completion on December 31, 2019.

- Operating Year 1 (OY1) = January 1, 2020 – December 31, 2020 (CY2020)
- Operating Year 2 (OY2) = January 1, 2021 – December 31, 2021 (CY2021)

Projected Utilization

In Section C, pages 15-18, the applicant provides the assumptions and methodology used to project utilization during the first two years of operation following project completion.

In-Center

BMA Lenoir	In-Center Dialysis
Begin with 107 Caldwell County in-center dialysis patients as of June 30, 2018.	107
Project growth of Caldwell County patient census by one half of Caldwell County Five Year Annual Change Rate for six months to December 31, 2018.	$107 \times 1.046 = 111.9$
Project growth of the Caldwell County patient census by the Caldwell County Five Year Annual Change Rate for 12 months to December 31, 2019.	$111.9 \times 1.091 = 122.0$
Add 10 patients from other counties. This is the starting census for this project.	$122.0 + 10 = 132.0$
Project growth of the Caldwell County patient census for one year to December 31, 2020.	$122.0 \times 1.091 = 133.2$
Add 10 patients from other counties. This is the end of Operating Year 1.	$133.2 + 10 = 143.2$
Project growth of the Caldwell County patient census for one year to December 31, 2021.	$133.2 \times 1.091 = 145.3$
Add 10 patients from other counties. This is the end of Operating Year 2.	$145.3 + 10 = 155.3$

Source: Section C, page 16

Projected patients for OY1 and OY2 are rounded down to the nearest whole number. Therefore, at the end of OY1 (CY2020) the facility is projected to serve 143 in-center patients and at the end of OY2 (CY2021) the facility is projected to serve 155 in-center patients.

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

- OY1: 3.4048 patients per station per week or 85.12% ($143 \text{ patients} / 42 \text{ stations} = 3.4048/4 = 0.8512$ or 85.12%)
- OY2: 3.6904 patients per station per week or 92.25% ($155 \text{ patients} / 42 \text{ stations} = 3.6904/4 = 0.9225$ or 92.25%)

The project utilization of 3.4048 patients per station per week at the end of OY1 is equal to or exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

Home Hemodialysis and Peritoneal Dialysis

- The applicant begins its utilization projections by using its PD and HHD patient census as of June 30, 2018.
- The applicant uses the Five-Year Average Annual Change Rate (AACR) for Caldwell County which is 9.1% to project the Caldwell County patient population forward.
- The applicant projects a growth rate equal to the Caldwell County Five-Year AACR of 9.1%.
- The applicant assumes no growth for patients living outside Caldwell County.
- Operating Year 1 (OY1) = January 1, 2020 – December 31, 2020 (CY2020)
 Operating Year 2 (OY2) = January 1, 2021 – December 31, 2021 (CY2021)

In Section C.1, page 17, the applicant provides the calculations it used to arrive at the projected PD and HHD patient census for OY1 and OY2, as summarized in the table below.

BMA Lenoir PD and HHD patients		
	PD	HHD
Begin with Caldwell County patients dialyzing at the facility as of June 30, 2018	8	1
Project growth of Caldwell County patient census by one half of Caldwell County Five Year Annual Change Rate for six months to December 31, 2018.	$8 \times 1.046 = 8.4$	$1 \times 1.046 = 1.05$
Project growth of the Caldwell County patient census by the Caldwell County Five Year Annual Change Rate for 12 months to December 31, 2019.	$8.4 \times 1.091 = 9.1$	$1.05 \times 1.091 = 1.14$
Add patients from other counties. This is the starting census for this project.	$9.1 + 1 = 10.1$	$1.1 + 1 = 2.1$
Project growth of the Caldwell County patient census for one year to December 31, 2020.	$10.1[9.1] \times 1.091 = 10.0[9.9]$	$1.1 \times 1.091 = 1.24$
Add the patients from other Counties. This is the ending census for Operating Year 1	$10.0[9.9] + 1 = 11[10.9]$	$1.2 + 1 = 2.2$
Project growth of the Caldwell County patient census for one year to December 31, 2021.	$10.0[9.9] \times 1.091 = 10.9 [10.8]$	$1.2 \times 1.091 = 1.36$
Add the patients from other Counties. This is the ending census for Operating Year 2	$10.9[10.8] + 1 = 11.9[11.8]$	$1.36 + 1 = 2.4$

Source: Tables in Section C, page 17

Projected utilization for all patients at BMA Lenoir is reasonable and adequately supported for the following reasons:

- The applicant begins its utilization projections with the existing in-patient, PD, and HHD census for Caldwell County for BMA Lenoir.
- The applicant uses the Five-Year Average Annual Change Rate (AACR) for Caldwell County which is 9.1% to project the Caldwell County patient population forward.
- The applicant projects a growth rate equal to the Caldwell County Five-Year AACR of 9.1%.
- The applicant assumes no growth for patients living outside Caldwell County.
- Projected utilization at the end of OY1 exceeds the minimum of 3.2 patients per station per week required by 10A NCAC 14C .2203(b).

Access

In Section C, page 18, the applicant states all of Fresenius related facilities in North Carolina have a history of providing dialysis services to the underserved population in North Carolina.

In Section L.1, page 50, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

BMA Lenoir Projected Payor Mix Project Year 2, CY 2021				
Payment Source	% Total Patients	% IC Patients	% HHD Patients	% PD Patients
Self-Pay/Indigent/Charity	1.19%	1.47%	0.00%	0.00%
Medicare	64.88%	62.28%	79.34%	79.34%
Medicaid	3.57%	4.12%	3.45%	3.45%
Commercial Insurance	6.55%	6.74%	8.89%	8.89%
Medicare/Commercial	16.67%	18.24%	3.73%	3.73%
Misc. (including VA)	7.14%	7.15%	4.60%	4.60%
Total	100.00%	100.00%	100.00%	100.00%

Note: Totals may not foot due to rounding.
 Source: Section L, page 50

As shown in the table above, during the second year of operation, the applicant projects that 82% of total services will be provided to Medicare patients (includes Medicare and Medicare/Commercial), and 3.6% to Medicaid patients.

Conclusion

The Agency reviewed the:

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

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

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

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

NA

The applicant does not propose to reduce or 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 the existing facility for a total of 42 stations upon completion of this project, and the following projects: Project ID # E-11528-18 (Change of Scope); Project ID # E-11401-17 (add seven stations); and Project ID# E-11377-17 (relocate BMA Lenoir).

In Section E, page 24, the applicant describes the alternatives it considered prior to submitting this application for the proposed project. The applicant states the only other alternative considered was maintaining the status quo, which is not an effective alternative because of the growth of the patient population dialyzing at BMA Lenoir.

The applicant states applying for an additional station is the most cost effective alternative because the project requires only a modest capital expense on behalf of BMA.

After considering the alternative, the applicant states the proposed project represented in the application is the most effective alternative to meet the identified need for one additional station 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 facility is operating at over 80% capacity as of the July 2018 SDR.
- The applicant utilizes the facility need methodology to show the need for additional stations.
- The applicant's projected utilization is reasonable and adequately supported. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- The applicant adequately demonstrates that maintaining the status quo is not the most effective alternative to meet the need for additional dialysis stations at BMA Lenoir because of the growth of the patient population dialyzing at BMA Lenoir.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Information which was publicly available during the review and used by the Agency
Therefore, the applicant adequately demonstrates that the application is conforming to this criterion and is approved subject to the following conditions.

- 1. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Lenoir shall materially comply with all representations made in the certificate of need application.**
- 2. Pursuant to the facility need determination in the July 2018 SDR, Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Lenoir shall develop no more than one additional dialysis stations for a total of no more than 42 certified stations at BMA Lenoir upon completion of this project, and the following projects: Project ID # E-11528-18 (Change of Scope); Project ID # E-11401-17 (add seven stations); and Project ID# E-11377-17 (relocate BMA Lenoir), which shall include any home hemodialysis training or isolation stations.**
- 3. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Lenoir shall install plumbing and electrical wiring through the walls for no more than one dialysis station which shall include any isolation stations.**

4. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Lenoir 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 the existing facility for a total of 42 stations upon completion of this project, and the following projects: Project ID # E-11528-18 (Change of Scope); Project ID # E-11401-17 (add seven stations); and Project ID# E-11377-17 (relocate BMA Lenoir).

Capital and Working Capital Costs

In Section F.1, page 26, the applicant projects the capital cost for the proposed project will be \$3,750 for water treatment equipment and furniture. The dialysis machines will be leased. In Sections F.10 and F.11, page 29, the applicant states that there are no projected start-up expenses or initial operating expenses because BMA Lenoir is an existing facility that is already operational.

Availability of Funds

In Section F.2, page 27, 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
Source: Section F, page 27

In Section F.2, page 28, the applicant states it will finance the capital costs with accumulated reserves. Exhibit F-1 contains a letter dated September 17, 2018 from the Senior Vice President and Treasurer of Fresenius Medical Care Holdings, Inc., authorizing and committing \$3,750 in capital costs for the project.

Exhibit F-2 contains a copy of Fresenius Medical Care Holdings, Inc. and Subsidiaries (FMC) Consolidated Financial Statements for the years ending December 31, 2017 and 2016. These

statements indicate that as of December 31, 2017, FMC had \$569,818,000 in cash and cash equivalents, \$19,822,127,000 in total assets and \$10,542,494,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project.

Financial Feasibility

The applicant provides pro forma financial statements for the first two years of the project. In the pro forma financial statement (Form B), the applicant projects that revenues will exceed operating expenses in the first two operating years, as shown in the table below.

Projected Revenues and Operating Expenses		
BMA Lenoir	Operating Year 1 CY 2020	Operating Year 2 CY 2021
Total Treatments	22,081	24,007
Total Gross Revenues (Charges)	\$88,059,028	\$95,739,916
Total Net Revenue	\$7,011,373	\$7,623,052
Average Net Revenue per Treatment	\$317	\$318
Total Operating Expenses (Costs)	\$5,369,410	\$5,631,532
Average Operating Expenses per Treatment	\$243	\$235
Net Income/Profit	\$1,641,963	\$1,991,520

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs, and charges. See Section R 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. 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.

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 because 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.

The applicant proposes to add one dialysis station to the existing facility for a total of 42 stations upon completion of this project, and the following projects: Project ID # E-11528-18 (Change of Scope); Project ID # E-11401-17 (add seven stations); and Project ID# E-11377-17 (relocate BMA Lenoir).

On page 365, the 2018 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 is Caldwell County. Facilities may serve residents of counties not included in their service area.

The applicant is the only provider of dialysis services in Caldwell County. According to the July 2018 SDR, there is one existing dialysis facility and one proposed dialysis facility in Caldwell County. However, Project ID # E-11528-18, approved a change of scope to the application to develop a new facility (Project ID # E-11376-17) and thus no new facility will be developed. Upon completion of all previously approved projects with the exception of E-11376-17 which will not be developed, BMA Lenoir will remain as one facility.

Facility Name	Provider Name	Location	# of Stations	Utilization
BMA Lenoir	Fresenius Medical Care	Lenoir	34	89.71%
FKC Caldwell County	Fresenius Medical Care	Hudson	14	N/A

Source: July 2018 SDR

In Section G, page 34, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Caldwell County. The applicant states:

“There is but a single dialysis facility operating in Caldwell County at this time. BMA has proposed to continue operations as a single dialysis facility.”

.....the July 2018 SDR reflects a three station deficit in Caldwell County. Adding one station will not duplicate services.”

The applicant adequately demonstrates that the proposal will not result in an unnecessary duplication of existing or approved services in the service area because the applicant adequately demonstrates that the proposed dialysis station is needed in addition to the existing and approved dialysis stations.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reason 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 H pages 35 and 37, the applicant provides current and projected staffing in full time equivalents (FTEs) for BMA Lenoir as demonstrated in the chart below. The applicant projects an increase in direct staffing in Operating Year 2. The applicant states the Medical Director is not directly employed by the facility, and thus is not reflected on the staffing chart.

BMA Lenoir facility staffing		
Position	Current # FTEs	Projected
	CY 2018	OY1 (CY2021)
Registered Nurse	6.00	6.50
Home Training Nurse	1.33	1.33
Patient Care Technician	14.00	16.00
Dietitian	1.00	1.00
Social Worker	1.00	1.00
Clinical Manager	1.00	1.00
Administration	0.15	0.15
In-Service	0.25	0.25
Clerical	1.00	1.00
Chief Tech	0.10	0.10
Equipment Tech	1.00	1.00
Total	26.83	29.33

The assumptions and methodology used to project staffing are provided in Section R. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, which is found in Section R. In Section H, page 36, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section I, page 40, the applicant identifies the current medical director. In Exhibit I-5, the applicant provides a letter from the current medical director indicating an interest in continuing to serve as medical director for the proposed services. In Section H, page 36, the applicant describes its physician recruitment plans. In Exhibit H-2, the applicant provides supporting documentation.

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.

C

In Section I, page 39, 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 – Necessary Ancillary and Support Services	
Services	Provider
In-center dialysis/maintenance	Bio-Medical Applications on site
Self-care training (in-center)	Bio-Medical Applications on site
Home training HH PD Accessible follow-up program	Bio-Medical Applications-on site
Psychological counseling	Catawba Valley Behavioral Health; New Directions; Happy Valley Clinic
Isolation – hepatitis	Bio-Medical Applications on site
Nutritional counseling	Bio-Medical Applications on site
Social Work services	Bio-Medical Applications on site
Acute dialysis in an acute care setting	Caldwell Memorial Hospital-Referral
Emergency care	Bio-Medical Applications, 911, Hospital
Blood bank services	Caldwell Memorial Hospital
Diagnostic and evaluation services	Caldwell Memorial Hospital
X-ray services	Caldwell Memorial Hospital
Laboratory services	Spectra
Pediatric nephrology	NC Baptist Hospital-Referral
Vascular surgery	Dr. Randal Bast; Foothills Dialysis Access Center-Referral
Transplantation services	Carolinas Health Care System-Referral
Vocational rehabilitation & counseling	Caldwell County Vocational Rehab Services-Referral
Transportation	Specialty Greenway Transportation; Premier Transportation; Regional Health Authority; Lakeview Transit Services

Source: Section I, page 39

In Section I, pages 40-41, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibits I-2, I-3 and I-4.

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.

NA

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

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and 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 53, the applicant provides the historical payor mix during Calendar Year 2017 (CY 2017) for its existing services, as shown in the table below.

BMA Lenoir Historical Payor Mix CY 2017	
Payment Source	% Total Patients
Self-Pay/Indigent/Charity	0.44%
Medicare	67.13%
Medicaid	4.05%
Commercial Insurance	7.19%
Medicare/Commercial	14.16%
Misc. (including VA)	7.02%
Other	0.44%
Total	100.00%

Source: Section L, page, 53

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant’s service area.

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate
Caldwell	19%	51%	12%	16%	14%	14%
Statewide	16%	51%	37%	15%	10%	12%

Source: <http://www.census.gov/quickfacts/table/US/PST045217>; Latest Data 7/1/17 as of 7/17/18

*Excludes "White alone, not Hispanic or Latino"

** "Estimates are not comparable to other geographical levels due to methodology differences that may exist between different data sources. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g. V2017) refers to the final year of the series (2010 thru 2017). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consisting of North Carolina, South Carolina and Georgia, provides an Annual Report which includes aggregate ESRD patient data from all three states. The report does not provide state-specific ESRD patient data, but the aggregate data is likely to be similar to North Carolina’s based on the Network’s recent annual reports which included state-specific data.

The IPRO SA Network 6 Annual Report (pages 25-26¹) provides the following prevalence data on dialysis patients by age, race, and gender. As of December 31, 2016, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 66% were other than Caucasian and 45% were female.

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 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

¹<https://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/07/NW6-2016-Annual-Report-FINAL.pdf>

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 52, the applicant states,

“Fresenius related facilities in North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations. The facility will be responsible to provide care to both minorities and handicapped people. The applicant will treat all patients the same regardless of race or handicapped status. In accepting payments from Medicare, Title XVIII of the Social Security Act, and Medicaid, Title XIX, all BMA North Carolina Facilities are obligated to meet federal requirements of the Civil Rights Act, Title VI and the Americans with Disabilities Act.”

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 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 Lenoir Projected Payor Mix Project Year 2, CY 2020				
Payment Source	% Total Patients	% IC Patients	% HHD Patients	% PD Patients
Self-Pay/Indigent/Charity	1.19%	1.47%	0.00%	0.00%
Medicare	64.88%	62.28%	79.34%	79.34%
Medicaid	3.57%	4.12%	3.45%	3.45%
Commercial Insurance	6.55%	6.74%	8.89%	8.89%
Medicare/Commercial	16.67%	18.24%	3.73%	3.73%
Misc. (including VA)	7.14%	7.15%	4.60%	4.60%
Total	100.00%	100.00%	100.00%	100.00%

Note: Totals may not foot due to rounding
 Source: Section L, page 50

As shown in the table above, during the second year of operation, the applicant projects that 82% of total services will be provided to Medicare patients (includes Medicare and Medicare/Commercial), and 3.6% to Medicaid patients.

On page 50, the applicant provides the assumptions and methodology it uses to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

- The projected payor mix is based on the historical payor mix.
- Projected utilization is reasonable and adequately supported. 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.

- (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.

In Section L, page 52, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section M.1, page 54, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M-1.

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 one dialysis station to the existing facility for a total of 42 stations upon completion of this project, and the following projects: Project ID # E-11528-18 (Change of Scope); Project ID # E-11401-17 (add seven stations); and Project ID# E-11377-17 (relocate BMA Lenoir).

On page 365, the 2018 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 is Caldwell County. Facilities may serve residents of counties not included in their service area.

The applicant is the only provider of dialysis services in Caldwell County. According to the July 2018 SDR, there is one existing dialysis facility and one proposed dialysis facility in Caldwell County. However, Project ID # E-11528-18, approved a change of scope to the application to develop a new facility (Project ID # E-11376-17) and thus no new facility will be developed. Upon completion of all previously approved projects with the exception of E-11376-17 which will not be developed, BMA Lenoir will remain as one facility.

Facility Name	Provider Name	Location	# of Stations	Utilization
BMA Lenoir	Fresenius Medical Care	Lenoir	34	89.71%
FKC Caldwell County	Fresenius Medical Care	Hudson	14	N/A

Source: July 2018 SDR

In Section N, page 55, 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. On page 56, the applicant states:

“The applicant does not expect this proposal to have 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 BMA Lenoir facility begins with the patients currently served by BMA at other BMA locations within the county, and a growth of that patient population consistent with the Caldwell County five year average annual change rate of 9.1% as published within the July [sic] 2018 SDR.

The facility also has added value stemming from the strength of our relationship with Blue Ridge Nephrology and Hypertension nephrology practice.

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

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 F and R of the application and any exhibits).
 - Quality services will be provided (see Section O of the application and any exhibits).
 - Access will be provided to underserved groups (see Section L of the application and any exhibits).
- (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 Exhibit A-4, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 114 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, no incidents related to quality of care 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 114 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 application is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services in 10A NCAC 14C .2200. The specific criteria are discussed below.

10A 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.1, pages 15-18, the applicant documents the need for the project and demonstrates that it will serve a total of 143 in-center patients on 42 stations at the end of the first operating year, which is 3.4048 patients per station per week or a utilization rate of 85.12 percent. The discussion regarding analysis of need 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 15-18, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.