

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 6, 2018

Findings Date: June 6, 2018

Project Analyst: Tanya S. Rupp

Team Leader: Gloria C. Hale

Assistant Chief: Lisa Pittman

Project ID #: N-11479-18

Facility: Lumberton Dialysis Unit

FID #: 955445

County: Robeson

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

Project: Add seven stations for a total of 22 dialysis stations upon completion of this project and Project ID #N-11447-18 (relocate 20 stations to the new FKC East Lumberton facility)

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., d/b/a Lumberton Dialysis Unit (“the applicant”, or “BMA Lumberton”) proposes to add seven dialysis stations to the existing facility, for a total of 22 certified dialysis stations upon completion of this project and Project ID #N-11447-18 (develop a new 20-station dialysis facility by relocating 20 existing dialysis stations and the home therapies program from BMA Lumberton to Fresenius Kidney Care (FKC) East Lumberton, which was approved on April 27, 2018). Since Project ID #N-11447-18 proposes the relocation of the home therapies program from BMA Lumberton, this application assumes no home therapies program once the home therapies program relocates to the new FKC East Lumberton facility December 31, 2019.

Need Determination

The 2018 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2018 Semiannual Dialysis Report (SDR), the county need methodology shows there is no county need determination for Robeson County. An applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology if the facility's utilization rate as reported in the latest SDR is at least 3.2 patients per station per week. The applicant is eligible to apply for additional stations based on the facility need methodology because the utilization rate reported for BMA Lumberton in the January 2018 SDR is 3.57.

Policies

There is one policy in the 2018 SMFP, Policy GEN-3, Basic Principles, which is applicable to this review.

Policy GEN-3: Basic Principles, on page 33, 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.”

The applicant addresses *Policy GEN-3* as follows:

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section B.4(a), page 8, Section O, pages 59 - 62, and Exhibit O-1. The information provided by the applicant is reasonable and adequately 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), page 9, Section C.3, pages 17 - 18, Section L, pages 51 - 54, and Exhibit L-1. The information provided by the applicant is reasonable and adequately 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 - 11 and Section N,

page 57. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would maximize healthcare value.

Conclusion

The Agency reviewed the:

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

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

- (2) Repealed effective January 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 seven dialysis stations to the existing facility, for a total of 22 certified dialysis stations upon completion of this project and Project ID #N-11447-18 (develop a new 20-station dialysis facility by relocating 20 existing dialysis stations and the home therapies program from BMA Lumberton to FKC East Lumberton).

Patient Origin

On page 365, the 2018 SMFP defines the service area for dialysis stations as *“the 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 Robeson County. Facilities may serve residents of counties not included in their service area.

In Section C.8, page 20, the applicant provides the historical in-center, home hemodialysis (HHD) and peritoneal dialysis (PD) patient origin for BMA Lumberton as of December 31, 2017, summarized in the following table:

**BMA Lumberton
 Historical Patient Origin 12/31/17**

COUNTY OF RESIDENCE	# IN-CTR PTS	# HHD PATIENTS	# PD PATIENTS
Robeson	121	7	10
Bladen	5	1	0
Cumberland	2	0	0
Hoke	0	0	1
Mecklenburg	1	0	0
Scotland	0	1	0
Other States	1	0	0
Total	130	9	11

In Section C.1, page 14, the applicant projects in-center patient origin for BMA Lumberton for the first two operating years (OY) following project completion, calendar years (CY) 2019 and 2020, as follows:

BMA Lumberton Projected Patient Origin

COUNTY	OY 1 (CY 2020)	OY 2 (CY 2021)	COUNTY PATIENTS AS % OF TOTAL	
			OY 1	OY 2
Robeson	71.2	74.4	91.0%	91.4%
Bladen	5	5	6.4%	6.1%
Cumberland	2	2	2.6%	2.5%
Total	78	81	100.0%	100.0%

The applicant rounds down to the nearest whole patient in its projections. In addition, the applicant provides the assumptions and methodologies used to project in-center patient origin in Section C.1, pages 14 - 15. The applicant adequately identifies the population to be served.

Analysis of Need

In Section C.1, page 14, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. In Section C.1, pages 14 - 15, the applicant describes its need methodology assumptions for projecting in-center utilization as follows:

1. The applicant projects growth of the Robeson County patient population by using the Robeson County Five Year Average Annual Change Rate (AACR) of 4.5% published in the January 2018 Semi-annual Dialysis Report (SDR).
2. The applicant projects 64 Robeson County ESRD patients will transfer their care to the new facility approved in Project ID #N-11447-18 effective January 1, 2020; therefore, the applicant will subtract 64 patients.
3. The applicant states two in-center patients from Mecklenburg County and one patient from out of state were dialyzing at BMA Lumberton as of December 31, 2017. The

applicant assumes those are transient patients and does not project those patients to continue to dialyze at the facility following the addition of stations.

4. The applicant states seven patients from Bladen and Cumberland counties were dialyzing at BMA Lumberton as of December 31, 2017. The applicant assumes these patients will continue to dialyze at the facility following the addition of stations; however, the applicant does not project growth in that patient population but adds them to the Robeson County population at the end of each project year.
5. The home therapies program will relocate to the new facility approved in Project ID #N-11447-18; therefore, there will be no growth in home therapies projected for BMA Lumberton in this application.
6. The project is scheduled to be complete on December 31, 2019; therefore, OY one is CY 2020, and OY two is CY 2021.

Projected Utilization of In-Center Patients

In Section C.1, page 15, the applicant provides the methodology used to project in-center patient utilization, as illustrated in the following table:

BMA Lumberton In-Center Patients, OY 1 and OY 2

Begin with Robeson County in-center patients as of December 31, 2017.	121
Project growth of Robeson County in-center patients for one year, to December 31, 2018, using the Robeson County Five Year AACR of 4.5%.	$121 \times 1.045 = 126.4$
Project growth of Robeson County in-center patients for one year, to December 31, 2019, using the Robeson County Five Year AACR of 4.5%.	$126.4 \times 1.045 = 132.1$
Subtract 64 patients projected to transfer their care to the new facility (FKC East Lumberton, Project ID #N-11447-18).	$132.8 - 64 = 68.1$
Add seven patients from Bladen and Cumberland Counties. This is the beginning patient census for the project.	$68.1 + 7 = 75.1$
Project growth of Robeson County in-center patients for one year, to December 31, 2020, using the Robeson County Five Year AACR of 4.5%.	$68.1 \times 1.045 = 71.2$
Add seven patients from Bladen and Cumberland Counties. This is the ending patient census for OY 1.	$71.2 + 7 = 78.2$
Project growth of Robeson County in-center patients for one year, to December 31, 2021, using the Robeson County Five Year AACR of 4.5%.	$71.2 \times 1.045 = 74.4$
Add seven patients from Bladen and Cumberland Counties. This is the ending patient census for OY 2.	$74.4 + 7 = 81.4$

On page 15, the applicant projects to serve 78 in-center dialysis patients on 22 stations at the end of OY 1, and 81 in-center dialysis patients on 22 stations at the end of OY 2, which is 3.5 patients per station per week at the end of OY 1 [78 patients / 22 stations = 3.5 patients per station per week], and 3.7 patients per station per week at the end of OY 2 [81 patients / 22 stations = 3.7 patients per station per week].

Therefore, the applicant’s projected in-center utilization exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

Projected Utilization of Peritoneal Dialysis and Home Hemo-Dialysis Patients

In Section C, page 16, the applicant projects utilization of the PD and HHD patients who will be served at BMA Lumberton until those modalities are relocated to FKC East Lumberton, as shown in the following tables:

BMA Lumberton PD Patients, OY 1 and OY 2

Begin with 10 Robeson County PD dialysis patients as of December 31, 2017.	10
Project growth of Robeson County PD patients for one year, to December 31, 2018, using the Robeson County Five Year AACR of 4.5%.	$10 \times 1.045 = 10.5$
Add one Hoke County patient.	$10.5 + 1 = 11.5$
Project growth of Robeson County PD patients for one year, to December 31, 2019, using the Robeson County Five Year AACR of 4.5%.	$10.5 \times 1.045 = 10.9$
Add one Hoke County patient.	$10.9 + 1 = 11.9$
The Home PD program is projected to relocate to FKC East Lumberton as of January 1, 2020.	0

BMA Lumberton HHD Patients, OY 1 and OY 2

Begin with 7 Robeson County HHD dialysis patients as of December 31, 2017.	7
Project growth of Robeson County HHD patients for one year, to December 31, 2018, using the Robeson County Five Year AACR of 4.5%.	$7 \times 1.045 = 7.3$
Add two patients from Bladen and Scotland counties.	$7.3 + 2 = 9.3$
Project growth of Robeson County HHD patients for one year, to December 31, 2019, using the Robeson County Five Year AACR of 4.5%.	$7.3 \times 1.045 = 7.6$
Add two patients from Bladen and Scotland counties.	$7.6 + 2 = 9.6$
The Home HD program is projected to relocate to FKC East Lumberton as of January 1, 2020.	0

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

- The applicant bases the future utilization of dialysis services upon the facility’s historical patient utilization, and
- The applicant utilizes the Robeson County Five Year AACR of 4.5% to project growth in patient utilization at the facility.

Access

In Section C.3, pages 17 - 18, the applicant states that Fresenius related facilities have a long history of serving the underserved population in the state and that each facility serves “*low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.*” The applicant further states that it will continue to provide access to low income and medically underinsured persons. In Section L.7, page 55, the applicant provides a table that illustrates 84.21% of FMC Lumberton’s total patients and 86.76% of the facility’s in-center patients were Medicare or Medicaid recipients in CY 2017. In supplemental information provided at the Agency’s request, the applicant projects that 86.76% of the facility’s patients will be Medicare or Medicaid recipients in OY 2.

On page 52, the applicant states that its projected payor mix is based on the historical payor mix for BMA Lumberton as of December 31, 2017.

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 a service
- eliminate a service
- 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 seven dialysis stations to the existing facility, for a total of 22 certified dialysis stations upon completion of this project and Project ID #N-11447-18 (develop a new 20-station dialysis facility by relocating 20 existing dialysis stations and the home therapies program from BMA Lumberton to FKC East Lumberton).

In Section E.1, pages 24 - 25, the applicant describes the alternatives considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo –The applicant states that maintaining the status quo is not an effective alternative because it would ignore the increasing dialysis patient population in Robeson County and at the facility. Maintaining the status quo would result in a utilization in excess of 100%, thereby necessitating a third shift.
- Apply for fewer than seven stations – The applicant states it considered applying for fewer than seven stations but rejected that alternative because BMA Lumberton’s utilization is projected to be over 80% at the end of the first operating year.
- Relocate Stations from Other BMA Facilities – The applicant states that it considered relocating dialysis stations from four of its other existing dialysis facilities in Robeson County but rejected that alternative because those facilities are already experiencing high utilization, or they are projected to have high utilization in the near future.

On page 25, the applicant states that its proposal is the most effective alternative because the project calls for replacing stations that have been relocated to develop a new facility pursuant to Project ID #N-11447-18 and will accommodate projected growth in patient census. Furthermore, this project will not have any capital costs associated with it. The applicant states this project seeks to ensure continued sufficiency of dialysis services in Robeson County.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative.

Conclusion

The Agency reviewed the:

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

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

- 1. Bio-Medical Applications of North Carolina, Inc. d/b/a Lumberton Dialysis Unit shall materially comply with all representations made in the certificate of need application and any supplemental responses. In the event that representations conflict, Bio-Medical Applications of North Carolina, Inc. d/b/a Lumberton Dialysis Unit shall materially comply with the last made representation.**
 - 2. Pursuant to the facility need determination in the January 2018 SDR, Bio-Medical Applications of North Carolina, Inc. d/b/a Lumberton Dialysis Unit shall develop no more than seven additional dialysis stations for a total of no more than 22 certified stations at Lumberton Dialysis Unit upon completion of this project and Project ID #N-11447-18, which shall include any home hemodialysis training or isolation stations.**
 - 3. Bio-Medical Applications of North Carolina, Inc. d/b/a Lumberton Dialysis Unit shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to the issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

BMA Lumberton proposes to add seven dialysis stations to the existing facility, for a total of 22 certified dialysis stations upon completion of this project and Project ID #N-11447-18 (develop a new 20-station dialysis facility by relocating 20 existing dialysis stations and the home therapies program from BMA Lumberton to FKC East Lumberton).

Capital and Working Capital Costs

In Section F.1, page 26, the applicant states that there will be no capital cost for the project. In Sections F.10 - F.12, pages 28 - 29, the applicant states there will be no start-up expenses or initial operating expenses incurred for this project since BMA Lumberton is an existing facility.

Financial Feasibility

The applicant provides pro forma financial statements for the first two operating years of the project following completion. In Form B, the applicant projects that operating expenses will exceed revenues in the first full operating year and revenues will exceed operating expenses in the second full operating year of the project, as shown in the table below.

BMA Lumberton		
	OY 1 (CY 2020)	OY 2 (CY 2021)
Total In-Center Treatments	11,263	11,707
Total Gross Revenues (Charges)	\$44,916,844	\$46,687,516
Deductions from Gross Revenues	\$41,637,330	\$43,278,720
Total Net Revenue	\$3,279,514	\$3,408,796
Average Net Revenue per Treatment	\$291.18	\$291.17
Total Operating Expenses (Costs)	\$3,280,015	\$3,380,699
Average Operating Expense per Treatment	\$291.22	\$288.78
Net Income (loss)	(\$502.00)	\$28,096

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.

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 demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

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

C

Bio-Medical Applications of North Carolina, Inc., d/b/a Lumberton Dialysis Unit (“the applicant”, or “BMA Lumberton”) proposes to add seven dialysis stations to the existing facility, for a total of 22 certified dialysis stations upon completion of this project and Project ID #N-11447-18 (develop a new 20-station dialysis facility by relocating 20 existing dialysis stations and the home therapies program from BMA Lumberton to FKC East Lumberton, which was approved on April 27, 2018).

On page 365, the 2018 SMFP defines the service area for dialysis stations as “*the 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 Robeson County. Facilities may serve residents of counties not included in their service area.

According to the January 2018 SDR, which reports information from the facilities as of June 30, 2017, there are six dialysis facilities in Robeson County: five are operated by the applicant or a related entity and one is operated by Total Renal Care of North Carolina, LLC (TRC). Information on all of these dialysis facilities, from Table B of the January 2018 SDR, is provided below:

**Robeson County Dialysis Facilities
 Certified Stations and Utilization as of June 30, 2017**

DIALYSIS FACILITY	PROVIDER	LOCATION	# OF CERTIFIED STATIONS	# PATIENTS	UTILIZATION
BMA of Red Springs	BMA	Red Springs	19	57	75.00%
FMC Dialysis Services of Robeson County	BMA	Fairmont	23	65	70.65%
FMC Pembroke	BMA	Pembroke	15	55	91.67%
FMC St. Pauls	BMA	St. Pauls	20	53	66.25%
Lumberton Dialysis Unit	BMA	Lumberton	35	125	89.29%
Maxton Dialysis*	TRC	Maxton	0	0	0.00%
St. Pauls Dialysis Center	TRC	St. Pauls	10	19	47.50%

Source: January 2018 SDR, Table B, page 45

*Maxton Dialysis is a replacement facility for St. Paul’s Dialysis Center, operated by TRC.

According to Table D in the January 2018 SDR, there is a deficit of nine dialysis stations in Robeson County. The applicant proposes to add seven dialysis stations to BMA Lumberton after 20 stations and the home therapies program were approved to be relocated pursuant to Project ID #N-11447-18. The addition of the seven stations as proposed in this application will decrease the deficit of dialysis stations in Robeson County. The applicant does not propose to establish a new facility. In Section G, pages 34 - 35, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Robeson County. On page 35, the applicant states:

“... the census in BMA facilities in Robeson County increased by 19 in-center patients, over the six months ended December 31, 2017. Utilization increased from 3.17 patients per station to 3.40 patients per station.”

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

- The proposal decreases the deficit of dialysis stations in Robeson County.
- The applicant adequately demonstrates that the addition of seven dialysis stations is needed at BMA Lumberton.

Conclusion

The Agency reviewed the:

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

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

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

C

In Section H.1, page 36, the applicant provides the current and projected staffing for the facility. The applicant states the number of full time equivalent (FTE) positions will decrease following the relocation of 20 stations in Project ID #N-11447-18, as shown in the following table:

BMA Lumberton Proposed Staffing

POSITION	CURRENT FTE POSITIONS	NUMBER TO BE DELETED	TOTAL FTE POSITIONS
Registered Nurse	7.00	-3.00	4.00
Home Training Nurse	2.00	-2.00	0.00
Patient Care Technician	16.00	-8.00	8.00
Dietician	1.00	0	1.00
Social Worker	1.00	0	1.00
Clinical Manager	1.00	0	1.00
Administrative (FMC Dir. of Ops)	0.20	0	0.20
In-Service	0.15	0	0.15
Clerical	2.00	0	2.00
Chief Technician	0.15	0	0.15
Equipment Technician	1.00	0	1.00
Total	31.50	-13.00	18.50

The assumptions and methodology used to project staffing are provided in Section H. 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 37, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section I, page 42, the applicant identifies the current medical director. In Exhibit I-5, the applicant provides a letter from the medical director indicating an interest in continuing to serve as medical director for the facility.

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

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion for 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.1, page 40, the applicant includes a list of providers of the necessary ancillary and support services, summarized as follows:

BMA LUMBERTON ANCILLARY AND SUPPORT SERVICES	
SERVICES	PROVIDER
In-center dialysis/maintenance	BMA
Self-care training (in-center)	Currently on site; to be referred to new FKC East Lumberton
Home training	
HH PD Accessible follow-up program	Currently on site; to be referred to new FKC East Lumberton
Psychological counseling	Robeson County Department of Social Services
Isolation – hepatitis	BMA
Nutritional counseling	BMA
Social Work services	BMA
Acute dialysis in an acute care setting	Southeastern Regional Medical Center
Emergency care	BMA / 911 / hospital
Blood bank services	Southeastern Regional Medical Center
Diagnostic and evaluation services	Southeastern Regional Medical Center
X-ray services	Southeastern Regional Medical Center
Laboratory services	Spectra Labs
Pediatric nephrology	UNC Pediatric Nephrology
Vascular surgery	Dr. Clinton Atkinson; Dr. Terry Lowery; Dr. Charles Anene; Dr. John Ross
Transplantation services	UNC Hospitals
Vocational rehabilitation & counseling	Robeson County Department of Social Services
Transportation	Southeast Area Transit System (SEATS); Robeson County Department of Social Services

In Section I.2, page 41, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibits I-1, I-2, I-3 and I-4. In addition, on page 42, the applicant provides a list of nephrologists who have agreed to provide medical coverage at the facility and who have expressed support for the project.

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

Conclusion

The Agency reviewed the following:

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

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

- (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 January 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 nor 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.7, page 55, the applicant provides the historical payor mix during CY 2017 at BMA Lumberton, as shown in the table below.

PAYOR CATEGORY	% OF TOTAL	% IN-CTR.	% HHD	% PD
Self Pay/Indigent/Charity	2.11%	2.49%	0.00%	0.00%
Medicare	72.63%	75.52%	66.42%	66.42%
Medicaid	7.37%	8.01%	2.83%	2.83%
Commercial Insurance	8.42%	6.67%	13.17%	13.17%
Medicare/Commercial	4.21%	3.23%	9.01%	9.01%
Miscellaneous (Incl. VA)	5.26%	4.08%	8.56%	8.56%
Total	100.00%	100.00%	100.00%	100.00%

Numbers may not sum due to rounding

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**
2016 Estimate	2016 Estimate	2016 Estimate	2016 Estimate	2015 Estimate	2011-2015	2015 Estimate
Robeson	14%	51%	75%	31%	13%	20%
Bladen	20%	52%	45%	25%	15%	17%
Cumberland	12%	52%	56%	19%	11%	11%
Statewide	16%	51%	37%	16%	10%	13%

Source: <http://www.census.gov/quickfacts/table> Latest Data 7/1/16 as of 8/22/17

*Excludes "White alone" who are "not Hispanic or Latino"

**"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. 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., V2016) refers to the final year of the series (2010 thru 2016). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consists of North Carolina, South Carolina and Georgia. IPRO SA Network 6

provides a 2015 Annual Report which includes aggregate ESRD patient data from all three states. However, a comparison of the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report*¹ percentages for North Carolina and the aggregate data for all three states in IPRO SA Network 6 shows very little variance; therefore the statistics for IPRO SA Network 6 are representative of North Carolina.

The IPRO SA Network 6 provides prevalence data on dialysis patients by age, race, and gender in its 2015 annual report, pages 27-28². In 2015, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 67% were non-Caucasian and 45% were female. (IPRO SA Network 6).

The Agency reviewed the:

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

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

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 53, the applicant states:

“Fresenius related 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 handicap status.”

¹<http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf>

²http://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/05/2015_NW-6_Annual-Report_Final-11-29-2016.pdf

In Section L, page 54, the applicant states that during the last five years no patient civil rights access complaints have been filed against any BMA North Carolina facilities.

The Agency reviewed the:

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

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

- (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 supplemental information provided at the Agency's request, 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 Lumberton
In-Center Patients Payor Mix
OY 2 (CY 2021)**

PAYOR CATEGORY	% OF TOTAL
Self Pay/Indigent/Charity	2.49%
Medicare	75.52%
Medicaid	8.01%
Commercial Insurance	6.67%
Medicare/Commercial	3.23%
Miscellaneous (Incl. VA)	4.08%
Total	100.00%

Numbers may not sum due to rounding

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 78.75% of total services will be provided to Medicare (Medicare and Medicare/Commercial) patients and 8.01% to Medicaid patients.

On page 52, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reason:

- the applicant states the projected payor mix is based on the historical experience of BMA Lumberton's recent patient census.

The Agency reviewed the:

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

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

- (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 54, the applicant adequately describes the range of means by which patients will have access to the proposed services, including physician referral.

The Agency reviewed the:

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

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

- (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 56, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-1.

The Agency reviewed the application and supporting exhibits. 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 January 1, 1987.
(16) Repealed effective January 1, 1987.
(17) Repealed effective January 1, 1987.

- (18) Repealed effective January 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

Bio-Medical Applications of North Carolina, Inc., d/b/a Lumberton Dialysis Unit (“the applicant”, or “BMA Lumberton”) proposes to add seven dialysis stations to the existing facility, for a total of 22 certified dialysis stations upon completion of this project and Project ID #N-11447-18 (develop a new 20-station dialysis facility by relocating 20 existing dialysis stations and the home therapies program from BMA Lumberton to FKC East Lumberton, which was approved on April 27, 2018).

On page 365, the 2018 SMFP defines the service area for dialysis stations as “*the 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 Robeson County. Facilities may serve residents of counties not included in their service area.

According to the January 2018 SDR, which reports information from the facilities as of June 30, 2017, there are six dialysis facilities in Robeson County: five are operated by the applicant or a related entity and one is operated by Total Renal Care of North Carolina, LLC (TRC). Information on all of these dialysis facilities, from Table B of the January 2018 SDR, is provided below:

**Robeson County Dialysis Facilities
 Certified Stations and Utilization as of June 30, 2017**

DIALYSIS FACILITY	PROVIDER	LOCATION	# OF CERTIFIED STATIONS	# PATIENTS	UTILIZATION
BMA of Red Springs	BMA	Red Springs	19	57	75.00%
FMC Dialysis Services of Robeson County	BMA	Fairmont	23	65	70.65%
FMC Pembroke	BMA	Pembroke	15	55	91.67%
FMC St. Pauls	BMA	St. Pauls	20	53	66.25%
Lumberton Dialysis Unit	BMA	Lumberton	35	125	89.29%
Maxton Dialysis*	TRC	Maxton	0	0	0.00%
St. Pauls Dialysis Center	TRC	St. Pauls	10	19	47.50%

Source: January 2018 SDR, Table B, page 45

*Maxton Dialysis is a replacement facility for St. Paul’s Dialysis Center, operated by TRC.

In Section N, pages 57 - 58, 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 57, the applicant states it anticipates the proposal will have no effect on competition in the service area, since it proposes to add stations to a facility from which stations were relocated. Furthermore, the applicant proposes to serve the in-center dialysis patient population that it has historically served.

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)

Conclusion

The Agency reviewed the:

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

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

- (19) Repealed effective January 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 O.3, page 62, the applicant states there are more than 100 Fresenius related dialysis facilities located in North Carolina.

In Section O.3, pages 62 - 63, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in one facility, BMA East Rocky Mount. On page 62, the applicant states that all of the problems have been corrected and the facility is back in full compliance with CMS Guidelines. After reviewing and considering information provided by the applicant and considering the quality of care provided at all Fresenius facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective January 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 promulgated in 10A NCAC 14C .2200. The specific criteria are discussed below:

10 NCAC 14C .2203 PERFORMANCE STANDARDS

- .2203(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- The applicant does not propose to establish a new End Stage Renal Disease facility. Therefore, this performance standard is not applicable to this review.
- .2203(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, page 14, the applicant projects to serve 78 in-center patients on 22 in-center stations by the end of OY 1, which is 3.54 patients per station per week [$78 / 22 = 3.54$]. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- .2203(c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section C.1, pages 14 - 15, 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.