

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: May 27, 2016

Findings Date: May 27, 2016

Project Analyst: Tanya S. Rupp

Team Leader: Fatimah Wilson

Project ID #: N-11136-16

Facility: BMA of Red Springs

FID #: 980754

County: Robeson

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

Project: Add three dialysis stations for a total of 15 dialysis stations upon project completion

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 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

The applicant, Bio-Medical Applications of North Carolina, Inc. d/b/a BMA of Red Springs proposes to add three dialysis stations to the existing facility for a total of 15 certified dialysis stations upon completion of the project. In Section C.9, page 21, the applicant states BMA Red Springs is not certified to provide home dialysis training. In Section C.1, page 18, the applicant states patients who are candidates for home dialysis are referred to BMA Lumberton, also in Robeson County.

#### **Need Determination**

The 2016 State Medical Facilities Plan (2016 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2016 Semiannual Dialysis Report (SDR), the county need methodology shows

there is no county need determination for additional dialysis stations in Robeson County. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology, because the utilization rate reported for BMA Red Springs in the January 2016 SDR is 3.67 patients per station per week. This utilization rate was calculated based on 44 in-center dialysis patients and 12 certified dialysis stations as of June 30, 2015 (44 patients / 12 stations = 3.67 patients per station per week). Application of the facility need methodology indicates three additional stations are needed for this facility, as illustrated in the following table:

<b>APRIL 1 REVIEW-JANUARY SDR</b>		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/15		91.67%
Certified Stations		12
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>12</b>
In-Center Patients as of 6/30/15 (SDR2)		44
In-Center Patients as of 12/31/14 (SDR1)		41
<b>Step</b>	<b>Description</b>	<b>Result</b>
	Difference (SDR2 - SDR1)	3
(i)	Multiply the difference by 2 for the projected net in-center change	6
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/14	0.1463
(ii)	Divide the result of step (i) by 12	0.0122
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/15 until 12/31/15)	0.0732
(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	47.2195
(v)	Divide the result of step (iv) by 3.2 patients per station	14.7561
	and subtract the number of certified and pending stations to determine the number of stations needed	<b>3</b>

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is three stations. 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 three new stations to the facility and, therefore, is consistent with the facility need determination for dialysis stations.

**Policies**

There is one policy in the 2016 SMFP which is applicable to this review: Policy GEN-3: Basic Principles. 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.”*

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), pages 12 - 13, Section O, pages 60 - 63, and referenced exhibits. 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 14, Section L, pages 52 - 53, and referenced exhibits. 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 14 - 15, and Section N, page 58. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

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

### **Conclusion**

In summary, the applicant adequately demonstrates that the application is consistent with the facility need determination in the January 2016 SDR and with Policy GEN-3 in the 2016 SMFP. Therefore, the application is conforming to this criterion.

- (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 three in-center dialysis stations to the existing facility for a total of 15 certified in-center dialysis stations upon completion of the project. In Section C.9, page 21, the applicant states BMA Red Springs is not certified to provide home dialysis training. In Section C.1, page 18, the applicant states patients who are candidates for home dialysis are referred to BMA Lumberton, also in Robeson County.

**Population to be Served**

On page 369, the 2016 SMFP defines the service area for dialysis stations as: *“the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.”* Thus, the service area for BMA Red Springs is Robeson County. Facilities may serve residents of counties not included in their service area.

In Section C.8, page 21, the applicant provides the current (as of December 31, 2015) in-center patient origin for BMA Red Springs, as illustrated in the following table:

**BMA Red Springs Patient Origin  
 as of December 31, 2015**

COUNTY	IN-CENTER PATIENTS
Robeson	47
Hoke	2
<b>Total</b>	<b>49</b>

In Section C.1, page 18, the applicant states the BMA Red Springs facility only serves in-center dialysis patients. Patients in need of home training are referred to BMA Lumberton, also in Robeson County. The applicant provides the projected patient origin for BMA Red Springs for the first two years of operation following completion of the project as follows:

**BMA Red Springs Projected Patient Origin, CY 2017 – CY 2018**

COUNTY	OY 1 (CY 2017)	OY 2 (CY 2018)	COUNTY PATIENTS AS % OF TOTAL	
	IN-CENTER PTS	IN-CENTER PTS	OY 1	OY 2
Robeson	51.7	54	96.3%	96.4%
Hoke	2	2	3.7%	3.6%
<b>Total</b>	<b>53.7</b>	<b>56</b>	<b>100.0%</b>	<b>100.0%</b>

The applicant provides the assumptions and methodology used to project patient origin in Section C.1, pages 18 - 19. The applicant adequately identifies the population to be served.

**Analysis of Need**

In Section B.2, pages 9 - 10, the applicant states the application is filed pursuant to the facility need methodology in the 2016 SMFP, utilizing data from the January 2016 SDR. The applicant proposes to add three dialysis stations to BMA Red Springs for a total of 15 certified stations

upon project completion. The applicant used the following assumptions from Section C.1, pages 18 – 19, as summarized below:

- The applicant assumes the portion of the patient population from Robeson County that comprises BMA Red Springs is part of the entire Robeson County dialysis patient population. Furthermore, the applicant assumes the BMA Red Springs Robeson County patient population will increase at a rate of 4.9%, the same rate as the Five Year Average Annual Change Rate (AACR) published in the January 2016 SDR.
- The applicant assumes that patients from other counties who dialyze at BMA Red Springs do so by choice, and that those patients will continue to dialyze at BMA Red Springs following the addition of the three stations. However, the applicant chose not to project an increase in the patient population from outside Robeson County; instead, it adds the existing two patients at the end of its growth projections for Robeson County patients.
- The applicant projects the project will be complete by December 31, 2016. Therefore, the first Operating Year (OY) is CY 2017 and the second Operating Year is CY 2018.

Projected Utilization

In Section C.1, page 19, the applicant begins with the Robeson County patient census as of December 31, 2015, and projects the following utilization for BMA Red Springs forward with the addition of the three stations:

Begin with Robeson County patients dialyzing at BMA Red Springs as of 12/31/15.	47
Project patient census forward one year to 12/31/16, using the Robeson County Five Year AACR.	$47 \times 1.049 = 49.3$
Project patient census forward one year to 12/31/17, using the Robeson County Five Year AACR.	$49.3 \times 1.049 = 51.7$
Add the two Hoke County patients currently dialyzing at BMA Red Springs (OY 1).	$51.7 + 2 = 53.7$
Project Robeson County patient census forward one year to 12/31/18.	$51.7 \times 1.049 = 54.3$
Add the two Hoke County patients currently dialyzing at BMA Red Springs (OY 2).	$54.3 + 2 = 56.3$

The applicant projects to serve 53 in-center patients on 15 stations or 3.5 patients per station per week ( $53 / 15 = 3.5$ ) by the end of Operating Year 1 and 56 in-center patients or 3.7 patients per station per week ( $56 / 15 = 3.7$ ) by the end of Operating Year 2 for the proposed 15-station facility. This 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). The applicant’s projected utilization is reasonable and adequately supported.

Access

In Section L.1(a), pages 52 - 53, the applicant states that each of BMA’s 104 facilities in 42 North Carolina Counties has a patient population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, and other underserved persons. On page 53 the applicant states Medicare represented 81.38% of treatments in all of its North Carolina facilities

in FY 2015. On page 56, the applicant states that 90.4% of its in-center patients at BMA Red Springs were recipients of Medicare or Medicaid in FY 2015; and on page 53 projects that 90.4% of its BMA Red Springs in-center patients be will be Medicare or Medicaid recipients in OY 2. The applicant adequately demonstrates the extent to which all residents of the service area, including underserved groups, are likely to have access to its services.

### **Conclusion**

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for three additional in-center stations at BMA Red Springs, and demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the services proposed. Therefore, the application is conforming to this criterion.

- (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

- (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

In Section E.1, page 25, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

- Maintain the Status Quo –The applicant states that maintaining the status quo is not an effective alternative because it ignores the needs of the patients dialyzing at BMA Red Springs. The applicant states failure to expand the facility will result in lack of capacity and failure to accept patient admissions.
- Apply for Fewer Stations – The applicant states it rejected this alternative because fewer stations would not effectively meet the projected utilization for the facility, particularly since the utilization is projected to be in excess of 80% by OY 1 [ $53 / 15 = 3.5$ ;  $3.5 / 4 = 0.88$ ].

After considering those alternatives, the applicant states the alternative represented in the application is the most effective alternative to meet the identified need.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that this proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

1. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA of Red Springs shall materially comply with all representations made in the certificate of need application.**
  2. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA of Red Springs shall add no more than three dialysis stations for a total of 15 stations, which shall include any home hemodialysis or isolation stations.**
  3. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA of Red Springs shall install plumbing and electrical wiring through the walls for no more than three dialysis stations, which shall include any isolation or home hemodialysis stations.**
  4. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA of Red Springs 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 three dialysis stations to the existing facility for a total of 15 certified stations upon project completion.

**Capital and Working Capital Costs**

In Section F.1, page 27, the applicant provides the following table to illustrate the capital cost for the project:

<b>Item</b>	<b>Cost</b>
Reverse Osmosis Water Treatment Equipment	\$ 2,250
Equipment/Furniture	\$11,350
<b>Total</b>	<b>\$13,600</b>

In Section F.10, page 30, the applicant states it will not incur start-up costs or initial operating costs since BMA Red Springs is currently operational.

**Availability of Funds**

In Section F.5, page 29, the applicant states it will use accumulated reserves to finance the project. In Exhibit F-1, the applicant provides a March 15, 2016 letter signed by the Vice

President and Treasurer of Fresenius Medical Care Holdings, Inc., which confirms the availability of sufficient funds for the completion of the project, and confirms the commitment of those funds for the development of the project.

In F.8, page 29, the applicant refers to Exhibit F-3 for a list of all projects currently under development being funded by Fresenius Medical Care Holdings, Inc. The applicant states all projects are funded with accumulated reserves and are not affected by one another.

In Exhibit F-2 the applicant provides a copy of the most recent audited FMC Holdings, Inc, financial statements (years ended December 31, 2013 and 2014). As of December 31, 2014, Fresenius Medical Care Holdings, Inc. and Subsidiaries had \$195,280,000 in cash and cash equivalents with \$18,507,042,000 in total equity and \$8,428,400,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project.

**Financial Feasibility**

In Section R, Form C, page 76, the applicant provides the following allowable charges per treatment for each payor source in the first and second years of operation:

PAYOR	IN-CENTER CHARGE
Self-Pay/Indigent/Charity	\$164.31
Medicare	\$230.08
Medicaid	\$283.29
Medicare Commercial	\$313.05
Commercial Insurance	\$977.79
VA	\$401.08

In Section R, page 77, the applicant states it used an average number of in-center patients, rounded down to the nearest whole number, to calculate revenues for the first and second operating years. The applicant states it reduces that figure by 5% for a missed treatment allowance. In Section R, Form B, page 74, he applicant projects revenues and expenses, as summarized in the table below:

BMA OF RED SPRINGS	OY 1 CY 2017	OY 2 CY 2018
Gross Revenue	\$30,731,528	\$32,506,188
Deductions from Gross Revenue	\$27,411,319	\$28,994,246
Total Revenue	\$ 3,320,209	\$ 3,511,942
Total Operating Expenses	\$ 2,554,079	\$ 2,680,147
<b>Net Profit</b>	\$ 766,130	\$ 831,794

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable and adequately supported, including the projected number of treatments. See the financial section of the application for the assumptions used regarding costs and charges. The discussions regarding analysis of need and projected utilization found in Criterion (3) are incorporated herein by reference.

In Section H, page 38, the applicant provides projected staffing and salaries. Form A in Section R, page one, shows budgeted operating costs adequate to cover the projected staffing. The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

**Conclusion**

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the proposal and adequately demonstrates that the financial feasibility of the project is based on reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

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

C

The applicant proposes to add three in-center dialysis stations to the existing facility for a total of 15 certified in-center dialysis stations upon completion of the project.

On page 369, the 2016 SMFP defines the service area for dialysis stations as “*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area for BMA Red Springs is Robeson County. Facilities may serve residents of counties not included in their service area.

The applicant currently operates five dialysis facilities in Robeson County. In addition, there is one other dialysis facility in Robeson County, as shown in the table below:

DIALYSIS FACILITY	PROVIDER	# CERTIFIED STATIONS IN JANUARY 2016 SDR	PATIENTS PER STATION	% UTILIZATION	ADDITIONAL STATIONS ADDED OR (DEDUCTED)
BMA of Red Springs	BMA	12	3.67	91.67%	--
FMC Dialysis Services of Robeson County	BMA	23	3.09	77.17%	--
FMC Pembroke	BMA	15	3.53	88.33%	--
FMC St. Pauls	BMA	15	3.80	95.00%	+ 5 <sup>1</sup>
Lumberton Dialysis Unit	BMA	35	3.43	85.71%	--
Maxton Dialysis*	DaVita	0	0.00	0.00%	+ 4 <sup>2</sup>
St. Pauls Dialysis Center*	DaVita	10	1.60	40.00%	--

\*DaVita was approved in February 2016 (Project ID #N-10321-14) to relocate and rename the St. Pauls Dialysis Center to Maxton Dialysis.

<sup>1</sup>In Project ID #N-11098-15 the applicant received a CON effective 3/8/16 to add five stations for a total of 20

<sup>2</sup>In Project ID #N-11077-15 the applicant received a CON effective 3/6/16 to relocate four stations to Maxton Dialysis Center for a total of 14

As shown in the table above, four of the six operational Robeson County dialysis facilities are operating above 80% utilization (3.2 patients per station), and five of the six facilities are operating above 77% utilization (3.1 patients per station, rounded). This is based on the assumption that dialysis facilities that operate four shifts per week (2 per day on alternate days) have a capacity of four patients per station per week.

The applicant proposes to add three stations to the existing facility pursuant to the facility need methodology. In Section C.1, pages 18 - 19, the applicant provides reasonable projections for the in-center patient population it proposes to serve. The applicant's growth projections are based on Robeson County's Five Year Average Annual Change Rate (AACR) in the January 2016 SDR. The applicant adequately demonstrates the need to add three stations to BMA Red Springs based on the number of in-center patients it proposes to serve.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved dialysis stations or facilities in Robeson County. Therefore, the application is conforming to this criterion.

- (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 38, the applicant provides the proposed staffing for the facility, as shown in the following table:

POSITION	# EXISTING FTE POSITIONS	# FTE POSITIONS TO BE ADDED	# TOTAL FTE POSITIONS
Registered Nurse	2.00	0.50	2.50
Patient Care Technician	5.00	1.00	6.00
Clinical Manager	1.00	--	1.00
Administrator	0.15	--	0.15
Dietician	0.50	--	0.50
Social Worker	0.50	--	0.50
Chief Technician	0.10	--	0.10
Equipment Technician	0.65	0.15	0.80
In-Service	0.15	0.05	0.20
Clerical	0.75	--	0.75
<b>Total</b>	<b>10.80</b>	<b>1.70</b>	<b>12.50</b>

As shown in the table above, the applicant proposes to add 1.70 FTE positions to the existing facility for a total of 12.50 FTE positions following project completion. In Sections H.3 and H.4, page 39, the applicant describes its experience in and processes for recruiting, training and retaining staff. In Section I.2, page 43, the applicant identifies Ezra McConnell, M.D. as the Medical Director for the facility. Exhibit I-7 contains a copy of a letter from Dr. McConnell, expressing his interest in continuing to serve as the Medical Director for the proposed facility. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

- (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 42, the applicant includes a list of providers of the necessary ancillary and support services for the patients who dialyze at the facility. The applicant adequately demonstrates that the necessary ancillary and support services will continue to be available and that the proposed services will be continue to be coordinated with the existing health care system. Therefore, 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

- (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

- (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

- (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 56, the applicant reports that 90.4% of the in-center patients who received treatments at BMA Red Springs in CY 2015 had some or all of their services paid for by Medicare or Medicaid in the past year. The table below shows the historical (CY 2015) payment sources as follows:

**BMA Red Springs Historical Payor Mix CY 2015**

PAYMENT SOURCE	IN-CENTER
Private Pay	5.06%
Commercial Insurance	3.72%
Medicare	76.47%
Medicaid	9.26%
VA	0.82%
Medicare/Commercial Insurance	4.67%
<b>Total</b>	<b>100.0%</b>

\*Numbers may not foot 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 & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
Robeson	13%	52%	73%	33%	13%	25%
Hoke	8%	51%	59%	20%	11%	21%
Statewide	15%	51%	36%	17%	10%	15%

Source: <http://www.census.gov/quickfacts/table, 2014 Estimate as of December 22, 2015>.

\*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., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

The *Southeastern Kidney Council Network 6 Inc. Annual Report* provides prevalence data on North Carolina dialysis patients by age, race, and gender on page 59, summarized as follows:

<b>Number and Percent of Dialysis Patients by Age, Race, and Gender 2014</b>		
	<b># of ESRD Patients</b>	<b>% of Dialysis Population</b>
<b>Age</b>		
0-19	52	0.3%
20-34	770	4.8%
35-44	1,547	9.7%
45-54	2,853	17.8%
55-64	4,175	26.1%
65+	6,601	41.3%
<b>Gender</b>		
Female	7,064	44.2%
Male	8,934	55.8%
<b>Race</b>		
African-American	9,855	61.6%
White	5,778	36.1%
Other, inc. not specified	365	2.3%

Source: <http://www.esrdnetwork6.org/utills/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older and over 63% were non-Caucasian. (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59*).

The applicant demonstrates that it currently provides adequate access to medically underserved populations. 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

In Section L.3(e), page 54, the applicant states:

*“BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations. ... The applicant will treat all patients the same regardless of race or handicap status.”*

In Section L.6, page 55, the applicant states there have been no civil rights access complaints filed within the last five years. Therefore, 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.1(b), page 52, the applicant projects that 90.4% of the in-center patients who will receive treatments at BMA Red Springs in the second operating year (FY 2019) will have some or all of their services paid for by Medicare or Medicaid. The applicant states this projection is based on treatment volumes at that facility. The table below shows the projected OY 2 payment source for each dialysis modality:

**BMA Red Springs Projected Payor Mix OY 2**

<b>PAYMENT SOURCE</b>	<b>IN-CENTER</b>
Private Pay	5.06%
Commercial Insurance	3.72%
Medicare	76.47%
Medicaid	9.26%
VA	0.82%
Medicare/Commercial Insurance	4.67%
<b>Total</b>	<b>100.0%</b>

The applicant’s projected payment sources are consistent with the applicant’s historical payment sources as reported in Section L.7, page 56. The applicant demonstrates that medically underserved groups will continue to have adequate access to the dialysis services proposed at BMA Red Springs. Therefore, 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.4, page 55, the applicant describes the range of means by which a person will have access to the dialysis services at BMA Red Springs, including referrals from nephrologists, other physicians, or hospital emergency rooms. The applicant adequately

demonstrates that the facility will offer a range of means by which patients will have access to dialysis services. Therefore, 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 57, the applicant states that it has communicated with local student nursing programs to offer the facility as a clinical training site for nursing students. Exhibit M-1 contains a copy of correspondence to Robeson Technical Community College documenting the offer of the facility as clinical training site. The information provided is reasonable and adequately supports a determination that 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 three in-center dialysis stations to the existing facility for a total of 15 certified in-center dialysis stations upon completion of the project.

On page 369, the 2016 SMFP defines the service area for dialysis stations as: *“the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.”* Thus, the service area for BMA Red Springs is Robeson County. Facilities may serve residents of counties not included in their service area.

The applicant currently operates five dialysis facilities in Robeson County. In addition, there is one other dialysis facility in Robeson County, as shown in the table below:

DIALYSIS FACILITY	PROVIDER	# CERTIFIED STATIONS IN JANUARY 2016 SDR	PATIENTS PER STATION	% UTILIZATION	ADDITIONAL STATIONS ADDED OR (DEDUCTED)
BMA of Red Springs	BMA	12	3.67	91.67%	--
FMC Dialysis Services of Robeson County	BMA	23	3.09	77.17%	--
FMC Pembroke	BMA	15	3.53	88.33%	--
FMC St. Pauls	BMA	15	3.80	95.00%	+ 5 <sup>1</sup>
Lumberton Dialysis Unit	BMA	35	3.43	85.71%	--
Maxton Dialysis*	DaVita	0	0.00	0.00%	+ 4 <sup>2</sup>
St. Pauls Dialysis Center*	DaVita	10	1.60	40.00%	--

\*DaVita was approved in February 2016 (Project ID #N-10321-14) to relocate and rename the St. Pauls Dialysis Center to Maxton Dialysis

<sup>1</sup>In Project ID #N-11098-15 the applicant received a CON effective 3/8/16 to add five stations for a total of 20

<sup>2</sup>In Project ID #N-11077-15 the applicant received a CON effective 3/6/16 to relocate four stations to Maxton Dialysis Center for a total of 14

As shown in the table above, 4 of the 6 operational Robeson County dialysis facilities are operating above 80% utilization (3.2 patients per station), and five of the six facilities are operating above 77% utilization (3.1 patients per station, rounded). This is based on the assumption that dialysis facilities that operate four shifts per week (2 per day on alternate days) have a capacity of four patients per station per week.

In Section N.1, page 58, the applicant discusses how any enhanced competition will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states:

*“BMA does not expect this proposal to have effect on the competitive climate in Robeson County. BMA does not project to serve dialysis patients currently being served by another provider. The projected population for the BMA Red Springs facility begins with patients currently served by BMA, and a growth of that patient population consistent with the Robeson County five year average annual change rate of 4.9% as published within the January 2016 SDR.*

...

*BMA facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid. The majority of our patients rely upon Medicare and Medicaid to cover the expense of their treatments. In this application, BMA projects that greater than 90% of the In-center patients will be relying upon government payors (Medicare/Medicaid/VA). The facility must capitalize upon every opportunity for efficiency.*

*BMA facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients. ... This proposal*

*will certainly not adversely affect quality, but rather, enhance the quality of the ESRD patients' lives by offering another convenient venue for dialysis care and treatment."*

See also Sections B, C, E, F, G, H and L in which the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information in the application is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on the cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need for the project and that it is a cost-effective alternative. The discussions regarding the analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates it will provide quality services. The discussion regarding quality found in Criteria (1) and (20) is incorporated herein by reference.
- The applicant demonstrates that it will provide adequate access to medically underserved populations. The discussion regarding access found in Criteria (1), (3) and (13) is incorporated herein by reference.

Therefore, the application is conforming to this criterion.

(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 and operated by the applicant or an affiliated company. In Section O.3, pages 64 - 66, the applicant identifies two of its North Carolina facilities, BMA Lumberton and BMA East Charlotte, that were cited in the past 18 months for deficiencies in compliance with 42 CFR Part 494, the Centers for Medicare and Medicaid (CMS) Conditions for Coverage of ESRD facilities. On page 66, the applicant states both facilities are back in full compliance with CMS Guidelines as of the date of submission of this application. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. 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 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-

*(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- The applicant proposes to increase the number of in-center stations at Dunn Kidney Center pursuant to the facility need methodology. In Section P.1, page 68 and Section C.1, pages 18 - 19, the applicant projects the facility will dialyze 53 in-center patients on 15 stations in the first operating year, which is 3.5 patients per station.

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

-C- The applicant provides all assumptions, including the methodology by which patient utilization is projected, in Section C.1, pages 18 - 19.