

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: February 24, 2017

Findings Date: February 24, 2017

Project Analyst: Bernetta Thorne-Williams

Assistant Chief: Martha J. Frisone

Project ID #: J-11230-16

Facility: Johnston Dialysis Center

FID #: 944566

County: Johnston

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

Project: Add six dialysis stations for a total of 31 dialysis stations upon project completion

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Department 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 Johnston Dialysis Center (BMA Johnston) proposes to add six dialysis stations for a total of 31 certified dialysis stations upon project completion.

#### **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

July 2016 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of seven dialysis stations in Johnston County, thus the applicant cannot apply to add any additional stations based on the county need methodology. However, the applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. 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 Johnston in the July 2016 SDR is 3.4 patients per station per week, or 85.0% (3.4 / 4 patients per station = 0.85). This utilization rate was calculated based on 85 in-center dialysis patients and 25 certified dialysis stations (85 patients / 25 stations = 3.4 patients per station per week).

Application of the facility need methodology indicates additional stations are needed for this facility, as illustrated in the following table:

<b>OCTOBER 1 REVIEW-JULY SDR</b>		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/15		85.0%
Certified Stations		25
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>25</b>
In-Center Patients as of 12/31/15 (July 2016 SDR) (SDR2)		85
In-Center Patients as of 6/30/15 (Jan 2016 SDR) (SDR1)		79
Step	Description	Result
	Difference (SDR2 - SDR1)	6
(i)	Multiply the difference by 2 for the projected net in-center change	12
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/15	0.1519
(ii)	Divide the result of Step (i) by 12	0.0127
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/14 until 12/31/15)	0.1519
(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	97.9114
(v)	Divide the result of Step (iv) by 3.2 patients per station	30.5973
	and subtract the number of certified and pending stations to determine the number of stations needed	5.5973

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is six 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 six new stations, therefore the application 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* on page 39 of the 2016 SMFP is applicable to this review because the facility need methodology is applicable to this review. Policy GEN-3 states:

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

### **Promote Safety and Quality**

The applicant describes how it believes the proposed project would promote safety and quality in Section B.4, pages 12-13, and Section O, pages 58-62. 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, page 13, Section C, page 19, Section L, pages 50-54, 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, pages 13-14, Section C, pages 17-22, Section N, page 56, and referenced exhibits. 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. Therefore, the application is consistent with Policy GEN-3.

**Conclusion**

In summary, the applicant adequately demonstrates that the proposal is consistent with the facility need methodology in the July 2016 SDR and Policy GEN-3. 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 six dialysis station for a total of 31 certified dialysis stations upon project completion.

**Patient Origin**

On page 369, the 2016 SMFP defines the service area for dialysis services 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 North Carolina counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Johnston County. Facilities may also serve residents of counties not included in their service area.

In Section C, page 21, the applicant provides a table showing the historical patient origin for in-center (IC) patients served by BMA Johnston, as shown below:

**Dialysis Patients as of 6/30/2016**

COUNTY	IC PATIENTS
Johnston County	89
Wayne	1
Total	90

In Section C, page 17, the applicant identifies the patient population it proposes to serve during the first two years of operation following project completion, as illustrated in the table below. The applicant does not propose to serve home hemodialysis or peritoneal dialysis patients.

**Projected Patient Origin**

County	Operating Year 1 CY 2019	Operating Year 2 CY 2020	County Patients as a % of Total	
	IC	IC	OY1	OY2
Johnston	102.8	107.1	99.0%	99.1%
Wayne	1	1	1.0%	0.9%
Total	103.8	108.1	100.0%	100.0%

The applicant provides the assumptions and methodology for the projections above on pages 17-19.

The applicant adequately identifies the population it proposes to serve.

**Analysis of Need**

The applicant proposes to add six dialysis stations to the existing BMA Johnston facility for a total of 31 certified dialysis stations upon project completion. In Section B.2, page 10, the applicant states the application is filed pursuant to the facility need methodology in the 2016 SMFP utilizing data from the July 2016 SDR. In Section C.1, pages 17-19, the applicant provides the assumptions used to demonstrate the need for the project. The facility’s patients who reside in Johnston County have increased at a rate commensurate with the Five-Year Average Annual Change Rate for Johnston County, which is 4.2%. The applicant does not project growth of any patients residing in Wayne County; the one existing patient from Wayne County was added to the projected Johnston County patients at appropriate points in the methodology.

Operating Year 1 (OY1) = Calendar Year (CY) 2019  
 OY2 = CY2020

**Projected Utilization**

In Section C, page 18, the applicant provided the methodology used to project in-center utilization, as illustrated in the following table,

Begin with the Johnston County patients dialyzing at BMA Johnston as of June 30, 2016.	89
Project the patient population forward for six months to December 31, 2016.	$[89 \times (.042 / 12 \times 6)] + 89 = 90.9$
Project this patient population forward one year to December 31, 2017.	$(90.9 \times .042) + 90.9 = 94.7$
Project this patient population forward one year to December 31, 2018.	$(94.7 \times .042) + 94.7 = 98.7$
Add one patient from Wayne County. This is the beginning census.	$98.7 + 1 = 99.7$
Project Johnston County patient population forward one year to December 31, 2019.	$(98.7 \times .042) + 98.7 = 102.8$
<b>OY1:</b> Add one patient from Wayne County. This is the projected ending census for OY1.	$102.8 + 1 = 103.8$
Project Johnson County patient population forward one year to December 31, 2020.	$(102.8 \times .042) + 102.8 = 107.1$
<b>OY2:</b> Add one patient from Wayne County. This is the projected ending census for OY2.	$107.1 + 1 = 108.1$

The applicant projects that BMA Johnston will serve a total of 103 in-center patients at the end of OY1 for a utilization rate of 83.06% or 3.32 patients per station per week (103 patients / 31 stations = 3.3225 / 4 = 0.8306 or 83.06%). The projected utilization of 3.32 patients per station per week at the end of OY1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

*Home Hemodialysis and Peritoneal Dialysis*

On page 17, the applicant states that BMA Johnston does not offer a home hemodialysis or peritoneal dialysis training. The applicant further states on page 17 that those services are provided at FMC Stallings Station.

Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth at BMA Johnston upon project completion.

**Access**

In Section L, pages 50-51, the applicant states BMA has a long history of providing care and services to a population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, and other traditionally underserved persons. The applicant provides its historical payor mix for CY2015 on page 54, as illustrated below.

<b>Payment Source</b>	<b>Percent of Total Patients</b>
Private Pay	9.86%
Commercial Insurance	7.86%
Medicare	64.79%
Medicaid	7.10%
VA	2.97%
Other: Medicare Commercial Insurance	7.42%
<b>Total</b>	<b>100.0%</b>

On page 51, the applicant projects that 79.74% of its patients will be Medicare or Medicaid recipients. 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, adequately demonstrates the need that population has for the proposed in-center stations and the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services. 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 24, the applicant discusses the alternatives considered prior to submitting this application, which include:

1. Maintain the Status Quo - the applicant states that this option would result in higher utilization rates given the historical growth rate of the facility (15.9% over the last six months as reflected in the July and January 2016 SDRs).

2. Apply for Fewer Stations - Application of the facility need methodology indicated a need for an additional six stations based on the continued growing need for dialysis services at BMA Johnston.
3. Relocate Stations from FMC Four Oaks and/or FMC Stalling Station - The applicant states FMC Four Oaks utilization was 65.91% and FMC Stalling Station operated at 77.08% utilization as of June 30, 2016. Both facilities experienced an increase in their in-center patient census. Thus, the applicant concluded that it would not be in the patient's best interest to relocate stations from either FMC Four Oaks and/or FMC Stalling Station.

The applicant states the project as proposed in the application would ensure that the facility addresses the issues of growth and access to dialysis services by its patients. Therefore, the applicant believes that adding six dialysis stations at BMA Johnston 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 Johnston Dialysis Center shall materially comply with all representations made in the certificate of need application.**
- 2. Bio-Medical Applications of North Carolina, Inc. d/b/a Johnston Dialysis Center shall develop and operate no more than six additional dialysis stations at Johnston Dialysis Center for a total of no more than 31 certified dialysis stations which shall include any isolation or home hemodialysis training stations upon project completion.**
- 3. Bio-Medical Applications of North Carolina, Inc. d/b/a Johnston Dialysis Center shall install plumbing and electrical wiring through the walls for no more than six additional dialysis stations, which shall include any isolation or home hemodialysis training stations.**
- 4. Bio-Medical Applications of North Carolina, Inc. d/b/a Carolina Dialysis Center 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

BMA proposes to add six dialysis stations for a total of 31 certified dialysis stations at Johnston Dialysis Center upon project completion.

**Capital and Working Capital Costs**

In Section F, page 27, the applicant projects the capital cost for the proposed project, as summarized in the table below:

Construction Contract	\$689,037
Water treatment equipment	\$280,000
Equipment/furniture not included above	\$84,950
<b>Total</b>	<b>\$1,053,987</b>

In Section F, page 30, the applicant states that there are no working capital needs for the proposed project since BMA Johnston is an existing facility.

**Availability of Funds**

In Section F, page 28, the applicant states that accumulated reserves/owner's equity will be used to finance the proposed project. In Exhibit F-1, the applicant provides a letter dated September 15, 2016 from the Senior Vice President and Treasurer, Fresenius Medical Care Holdings, Inc., (FMC) which is the parent of National Medical Care, Inc. and Bio-Medical Applications of North Carolina, Inc., committing to fund the project's capital needs with its cash reserves.

Exhibit F-2 contains a copy of Fresenius Medical Care Holdings, Inc. and Subsidiaries (FMC) Consolidated Financial Statements for December 31, 2015 and December 31, 2014. As of December 31, 2015, FMC had \$249,300,000 in cash and cash equivalents, \$19,332,539 in total assets and \$10,144,288 in net assets (total assets less total liabilities).

The applicant adequately demonstrated the availability of sufficient funds for the capital needs of the project.

**Financial Feasibility**

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

<b>Johnson Dialysis Center</b>	<b>Operating Year 1 CY2019</b>	<b>Operating Year 2 CY2020</b>
Total Treatments	14,968	15,709
Total Gross Revenues (Charges)	\$59,692,384	\$62,647,492
Total Net Revenue	\$4,233,781	\$4,443,376
Total Operating Expenses (Costs)	\$3,970,607	\$4,139,796
<b>Net Profit</b>	<b>\$263,174</b>	<b>\$303,580</b>

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 for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based on reasonable projections of costs and charges.

**Conclusion**

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital and operating needs of the proposal and 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.

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BMA proposes to add six dialysis stations for a total of 31 certified dialysis stations at BMA Johnston following project completion.

On page 369, the 2016 SMFP defines the service area for dialysis services 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 North Carolina counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Johnston County. Facilities may also serve residents of counties not included in their service area.

The July 2016 SDR indicates there are three dialysis facilities in Johnston County, as follows:

**Johnston County Dialysis Facilities  
 as of December 31, 2015**

<b>Dialysis Facilities</b>	<b>Owner</b>	<b># of Patients</b>	<b>Location</b>	<b># of Certified Stations</b>	<b># of Approved Stations</b>	<b>Percent Utilization</b>
FMC Four Oaks	FMC	56	Four Oaks	22	0	63.64%
FMC Stallings Station	FMC	71	Clayton	24	0	73.96%
Johnston Dialysis Center	BMA	85	Smithfield	25	0	85.00%

As shown in the table above, all the facilities in Johnston County are operated by FMC. Based on the most recent SDR, all of the facilities in Johnston County were operating at greater than 60% of capacity as of December 31, 2016. BMA Johnston operated at 85% of capacity.

In Section C, pages 17-19, the applicant demonstrates that Johnston Dialysis Center will serve a total of 103 in-center patients at the end of OY1 for a utilization rate of 83.06% or 3.32 patients per station per week (103 patients / 31 stations = 3.3225 / 4 = 0.8306 or 83.06%). The projected utilization of 3.32 patients per station per week at the end of OY1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b). The applicant adequately demonstrates the need to add six additional stations at BMA Johnston 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 services in Johnston County. Consequently, 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, page 37, the applicant provides current and projected staffing in full time equivalents (FTEs) for BMA Johnston, as shown in the table below.

POSITION	CURRENT # FTEs	# FTEs POSITIONS ADDED/ DELETED	PROJECTED # FTEs
Registered Nurse	3.00	1.50	4.50
LPN	1.00		1.00
Technician (PCT))	8.00	4.00	12.00
Clinical Manager	1.00		1.00
Administrator	0.20		0.20
Dietician	0.65	0.20	0.85
Social Worker	0.65	0.20	0.85
Chief Tech	0.35		0.35
Equipment Tech	0.80	0.20	1.00
In-Service	0.35		0.35
Clerical	1.00	0.50	1.50
<b>Total</b>	<b>17.00</b>	<b>6.6</b>	<b>23.6</b>

In Section H, page 39, the applicant provides the projected direct care staff for BMA Johnston in OY2, as shown below in the table:

DIRECT CARE POSITIONS	# FTEs	HOURS PER YEAR PER FTE	TOTAL ANNUAL FTE HOURS	TOTAL ANNUAL HOURS OF OPERATION	# FTE HOURS PER HOUR OF OPERATION
Registered Nurse	4.50	2,080	9,360	3,120	3.00
LPN	1.00	2,080	2,080	3,120	0.667
Technician (PCT)	12.00	2,080	24,960	3,120	8.00
<b>Total</b>	<b>17.50</b>	<b>2,080</b>	<b>36,400</b>	<b>3,120</b>	<b>11.67</b>

In Section I, page 41, the applicant identifies Dr. William Fan as the Medical Director of the facility. In Exhibit I-5, the applicant provides a signed letter from Dr. Fan of Wake Nephrology supporting the project and confirming his commitment to serve as Medical Director. Exhibit I-6 contains a copy of Dr. Fan’s curriculum vitae. In Section H, pages 37, the applicant describes the methods used to recruit and fill vacant or new positions.

The applicant documents the availability of adequate health manpower and management personnel, including the Medical Director, for the provision of the proposed dialysis 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.

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In Section I, page 40, the applicant includes a list of providers of the necessary ancillary and support services. Exhibit I-5 contains a letter from the medical director of the facility expressing his support for the proposed project. The applicant discusses coordination with the existing health care system on pages 41-43. Exhibits I-2 through I-4, respectively, contain copies of agreements for Spectra laboratories services, Johnston Health, and UNC Hospitals for transplant services. The information in Section I and Exhibits I-2, I-3 and I-4 is reasonable and adequately supports a finding of conformity with 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.

C

In Section K.2, page 47, the applicant states the facility currently consists of 3,577 square feet of treatment area, which includes space for an isolation room. The applicant proposes to renovate/convert 1,029 square feet of existing space for a total treatment area space of 4,606 square feet, including space for the isolation room. The applicant provides line drawings of the proposed facility in Exhibit K-1. In Section F.1, page 27, the applicant lists its project costs, including \$689,037 for construction contract costs, \$280,000 for water treatment equipment and \$84,950 for equipment/furniture for a total project cost of \$1,053,987. In Section F, page 29, the applicant states the dialysis machines will be leased. In Section B.5, pages 15-16, the applicant describes how BMA Johnston will continue to ensure energy-efficiency and water conservation. Costs and charges are described by the applicant in Section F, pages 27-29, and in the pro forma financial statements in Section R. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference.

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, that energy saving features have been incorporated into the construction plans and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L, page 54, the applicant reports that 79.31% of the patients who received treatments at BMA Johnston had some or all of their services paid for by Medicare or Medicaid in CY 2015, as illustrated in the table below.

Payment Source	Percent of Total Patients
Private Pay	9.86%
Commercial Insurance	7.86%
Medicare	64.79%
Medicaid	7.10%
VA	2.97%
Other: Medicare Commercial Insurance	7.42%
<b>Total</b>	<b>100.0%</b>

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 Johnston County, Wayne County and statewide.

Percent of Population						
County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
Johnston	12%	51%	31%	15%	10%	19%
Wayne	15%	51%	46%	23%	12%	18%
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, incld'g. 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, page 52, the applicant states:

*“BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations.”*



In Section L.6, page 53, the applicant states that there have been no patient civil rights complaints filed against any BMA North Carolina facilities in the past five years.

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, page 50, the applicant states:

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

In Section L, page 51, the applicant projects that 79.74% of all patients who will receive dialysis treatments at BMA Johnston will have all or part of their services paid for by Medicare and or Medicaid, as illustrated below:

**BMA Johnston  
Projected Payor Mix OY2**

<b>Payment Source</b>	<b>Percent of Total Patients</b>
Private Pay	10.74%
Commercial Insurance	6.18%
Medicare	61.26%
Medicaid	8.72%
VA	3.34%
Other: Medicare Commercial Insurance	9.76%
<b>Total</b>	<b>100.0%</b>

The applicant demonstrates that medically underserved populations will have adequate access to the proposed services. 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 53, the applicant states:

*“Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. BMA-Johnston has an open policy, which means that any Nephrologist may apply to admit patient to the facility. The attending physicians receive referrals from other physicians or Nephrologists or hospital emergency rooms. ... Transient patients are accepted upon proper coordination of care with the patient’s regular nephrologist and a physician with staff privileges at the facility.”*

The applicant adequately demonstrates that it will offer a range of means by which patients will have access to the proposed 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 55 the applicant states that BMA Johnston has offered the facility as a site for clinical rotations for Johnston Community College’s nursing students. Exhibit M.I contains a copy of a letter from Fresenius Kidney Care to the Director of Nursing Education Programs of Johnston Community College documenting the offer.

The information provided in Section M.1 and Exhibit M-1 is reasonable and credible and supports a finding of conformity 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

BMA proposes to add six dialysis stations for a total of 31 certified dialysis stations and at BMA Johnston following completion of this project.

On page 369, the 2016 SMFP defines the service area for dialysis services 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 North Carolina counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Johnston County. Facilities may also serve residents of counties not included in their service area.

The July 2016 SDR indicates there are three dialysis facilities in Johnston County, as follows:

**Johnston County Dialysis Facilities  
 as of December 31, 2015**

<b>Dialysis Facilities</b>	<b>Owner</b>	<b># of Patients</b>	<b>Location</b>	<b># of Certified Stations</b>	<b># of Approved Stations</b>	<b>Percent Utilization</b>
FMC Four Oaks	FMC	56	Four Oaks	22	0	63.64%
FMC Stallings Station	FMC	71	Clayton	24	0	73.96%
Johnston Dialysis Center	BMA	85	Smithfield	25	0	85.00%

As shown in the table above, all the facilities in Johnston County are operated by FMC. Based on the most recent SDR, all of the facilities in Johnston County were operating at greater than 60% of capacity as of December 31, 2016. BMA Johnston operated at 85% of capacity.

In Section N, page 56, the applicant discusses how any enhanced competition in the service area will promote 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 Johnston County. BMA does not project to serve dialysis patients currently being served by another provider. The projected patient population for the BMA Johnston facility begins with patients currently served by BMA at other BMA locations within the county, and a growth of that patient population consistent with the Johnston County five year average annual change rate of 4.2% as published within the July 2016 SDR. ... At this time, BMA is the sole provider of dialysis services operating in Johnston County. ... This proposal will ... enhance the quality of the ESRD patients’ lives by offering another convenient venue for dialysis care and treatment.”*

See also Sections C, F, G, H, L and P where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicant in the sections referenced above 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 proposed in-center dialysis stations and that it is an effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates that BMA Johnston will continue to provide quality dialysis services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- The applicant demonstrates that BMA Johnston will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (1), (3) and (13) are 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 Section B, pages 12-13, Section O, pages 58-59, and Exhibit O-1, the applicant discusses the methods it uses to ensure and maintain quality. In Section O, pages 61-63, the applicant states that out of more than 100 facilities located in North Carolina operated by the applicant or a related entity, only the three listed below were not in compliance with Medicare conditions of participation during the 18 months prior to submission of the application.

<b>BMA QUALITY CARE</b>			
<b>FACILITY</b>	<b>SURVEY DATE</b>	<b>BACK IN COMPLIANCE</b>	
BMA Lumberton	5/6/2015	Yes	5/29/2015
BMA East Charlotte	8/11/2015	Yes	9/9/2015
RAI West College	3/15/2016	Yes	4/11/2016

Based on a review of this certificate of need application and publicly available information, 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 Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The application is conforming to all applicable criteria, as discussed below.

**10 NCAC 14C .2203 PERFORMANCE STANDARDS**

*.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- BMA Johnston is an existing facility.

*.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, pages 17-19, the applicant demonstrates that BMA Johnston will serve a total of 103 in-center patients at the end of OY1 for a utilization rate of 83.06% or 3.32 patients per station per week (103 patients / 31 stations = 3.322 / 4 = .8306 or 83.06%). The discussion regarding analysis of need 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 17-19, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.