

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: February 3, 2020

Findings Date: February 3, 2020

Project Analyst: Tanya M. Saporito

Assistant Chief: Lisa Pittman

Project ID #: J-11782-19

Facility: Johnston Dialysis Center

FID #: 030941

County: Johnston

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

Project: Add no more than 1 dialysis station for a total of no more than 33 stations upon completion of this project, Project ID #J-11407-17 (add one station), Project ID #J-11372-17 (relocate 4 stations to FKC Selma), and Project ID #J-11540-18 (relocate 4 stations from Zebulon Kidney Center)

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications of North Carolina, Inc. (hereinafter referred to as “the applicant” or BMA) proposes to add one dialysis station to Johnston Dialysis Center (Johnston Dialysis), an existing dialysis facility, for a total of 33 dialysis stations upon completion of this project and the following three projects:

- Project ID #J-11372-17 - Develop a new 10-station facility (FKC Selma) by relocating two dialysis stations from FMC Four Oaks, four from Johnston Dialysis and four from FMC New Hope Dialysis
- Project ID #J-11407-17 - add one station to Johnston Dialysis Center
- Project ID #J-11540-18 - relocate four stations from Zebulon Kidney Center to Johnston Dialysis Center

The Certificate of Need (CON) for Project ID #J-11540-18 is still under development; therefore, this application is being filed as a Change of Scope application, even though it is an application to add additional dialysis stations to Johnston Dialysis pursuant to the Facility Need Determination. The Project Analyst notes that the applicant refers to “Johnston Dialysis Center”, “BMA” and “BMA Johnston” interchangeably throughout the application. Each of the names refers to Johnston Dialysis Center.

### **Need Determination**

The 2019 State Medical Facilities Plan (2019 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table D, page 62, in the July 2019 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of 12 stations in Johnston County, but because there are facilities with a reported utilization of less than 80% in Table B of the 2019 SDR, there is no county need determination for new dialysis stations for Johnston County.

However, the applicant is eligible to apply for additional dialysis stations in an existing facility based on the facility need methodology if the utilization rate for that dialysis facility, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. The utilization rate reported for Johnston Dialysis in the July 2019 SDR is 3.45 patients per station per week, or 86.29%, based on 107 in-center dialysis patients and 31 certified dialysis stations [ $107 / 31 = 3.45$ ;  $3.45 / 4 = 0.8629$ ]. Therefore, Johnston Dialysis is eligible to apply for additional stations based on the facility need methodology.

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

**Johnston Dialysis Center**

Required SDR Utilization		80%
Center Utilization Rate as of 12/31/18		86.29%
Certified Stations		31
Pending Stations		5
<b>Total Existing and Pending Stations</b>		<b>36</b>
In-Center Patients as of 12/31/18 (July 2019 SDR) (SDR2)		107
In-Center Patients as of 6/30/18 (Jan 2019 SDR) (SDR1)		102
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	5
	Multiply the difference by 2 for the projected net in-center change	10
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/18	0.0980
(ii)	Divide the result of Step (i) by 12	0.0082
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/17 until 12/31/18)	0.0980
(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	117.4902
(v)	Divide the result of Step (iv) by 3.2 patients per station	36.7157
	and subtract the number of certified and pending stations to determine the number of stations needed	0.7157

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

**Policies**

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

Policy GEN-3, on page 31 of the 2019 SMFP, states:

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

### Promote Safety and Quality

The applicant describes how it believes the proposed project will promote safety and quality in Section B.3 (a and d), pages 12 and 14, respectively; Sections N.1 and N.2(b), pages 54 - 55; Section O, pages 57 - 60; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant's proposal will promote safety and quality.

### Promote Equitable Access

The applicant describes how it believes the proposed project will promote equitable access in Section B.3, pages 12 - 13; Section N.2(c), page 55; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant's proposal will promote equitable access.

### Maximize Healthcare Value

The applicant describes how it believes the proposed project will maximize healthcare value in Section B.3, pages 13 - 14; Sections N.1 and N.2(a), page 55; and referenced exhibits. The information provided by the applicant with regard to its efforts to maximize healthcare value is reasonable and supports the determination that the applicant's proposal will maximize healthcare value.

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

### Conclusion

The Agency reviewed the:

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

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

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

BMA proposes to add one dialysis stations to Johnston Dialysis, an existing dialysis facility, for a total of 33 dialysis stations upon completion of this project and the following three projects:

- Project ID #J-11372-17 - Develop a new 10-station facility (FKC Selma) by relocating two dialysis stations from FMC Four Oaks, four from Johnston Dialysis and four from FMC New Hope Dialysis
- Project ID #J-11407-17 - add one station to Johnston Dialysis Center
- Project ID #J-11540-18 - relocate four stations from Zebulon Kidney Center to Johnston Dialysis Center

The Certificate of Need (CON) for Project ID #J-11540-18 is still under development; therefore, this application is being filed as a Change of Scope application, even though it is an application to add additional dialysis stations to Johnston Dialysis pursuant to the Facility Need Determination.

**Patient Origin**

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

In Section C.2, page 17, the applicant provides the patient origin for Johnston Dialysis in-center (IC) patients as of December 31, 2018, as illustrated in the table below:

**Johnston Dialysis Historical Patient Origin  
January 1, 2018 – December 31, 2018**

COUNTY	# IN-CENTER PTS.	% OF TOTAL
Johnston	105	98.1%
Wilson	1	0.9%
Other States	1	0.9%
<b>Total</b>	<b>107</b>	<b>100.00%</b>

Totals may not sum due to rounding

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

**Johnston Dialysis Projected Patient Origin  
 January 1, 2022 – December 31, 2022**

COUNTY	# IN-CENTER PTS.	% OF TOTAL
Johnston	129.9	97.7%
Nash	1.0	0.8%
Wilson	2.0	1.5%
<b>Total</b>	<b>132.9</b>	<b>100.00%</b>

Totals may not sum due to rounding

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

**Analysis of Need**

In Section C.4, page 20 the applicant states that the need the proposed population has for the proposed services is a function of the individual patient need for dialysis care and treatment. In addition, the applicant states that dialysis treatment is necessary for patients with End Stage Renal Disease.

In Section C, pages 18 – 20 and Section Q, pages 69 - 71, the applicant provides the assumptions and methodology for projecting in-center patient utilization, summarized as follows:

- The applicant provides a table on pages 18 and 69 that shows the facility in-center census as of December 31, 2018 and June 30, 2019, as summarized below.

**JOHNSTON DIALYSIS  
 IN-CENTER PATIENTS**

COUNTY	12/31/2018	6/30/2019
Johnston	105	115
Wilson	1	2
Other States	1	0
<b>Total</b>	<b>107</b>	<b>117</b>

- The applicant states that it will begin its analysis with the Johnston Dialysis patient census as of June 30, 2019, which was submitted to the Agency on the ESRD Data Collection form in August 2019 and is shown in the table above.
- The applicant projects growth of the Johnston County patient population based on the 8.3% Johnston County Five Year Average Annual Change Rate (AACR) published in the July 2019 SDR.
- The applicant describes four other pending projects which it states are impacted by or which impact this project, as follows:

- Project ID #J-11372-17 – The applicant projected that 21 patients would transfer their care from Johnston Dialysis.
  - Project ID #J-11435-17 – The applicant projected that two patients would transfer their care from Johnston Dialysis.
  - Project ID #J-11739-19 – The applicant projected that three patients would transfer their care from Johnston Dialysis.
  - Project ID #J-11540-18 – The applicant projected seven Johnston County patients and one Nash County patient would transfer their care to Johnston Dialysis.
- The applicant states each of the changes described above is scheduled for December 31, 2020 and it will incorporate the changes into the projections of future patients to be served.
  - The applicant projects project completion by December 31, 2020. Therefore, Operating Year (OY) 1 is calendar year (CY) 2021, January 1 - December 31, 2021 and OY 2 is CY 2022, January 1 - December 31, 2022.

Projected Utilization

In Section C, page 19 and Section Q, page 70, the applicant provides the methodology it used to project utilization, based on its stated assumptions, as illustrated in the following table:

<b>JOHNSTON DIALYSIS IN-CENTER PATIENTS</b>	
Begin with Johnston County patient population as of June 30, 2019.	115
Project forward six months to December 31, 2019 using one-half of the Johnston County Five Year AACR in the July 2019 SDR of 8.3%.	$115 \times 1.0415 = 119.8$
Project forward one year to December 31, 2020 using Johnston County Five Year AACR of 8.3%.	$119.8 \times 1.083 = 129.7$
Subtract 26 patients as shown in the methodology.	$129.7 - 26 = 103.7$
Add seven patients residing in Johnston County and one patient in Nash County. Add two Wilson County patients dialyzing as of June 30, 2019. This is the projected beginning census for OY 1.	$103.7 + 7 + 1 + 2 = 113.7$
Project Johnston County population forward one year to December 31, 2021, using Johnston County Five Year AACR of 8.3%.	$(103.7 + 7) \times 1.083 = 119.9$
Add three patients from Nash and Wilson counties. This is ending census for OY 1.	$119.9 + 3 = 122.9$
Project Johnston County population forward one year to December 31, 2022, using Johnston County Five Year AACR of 8.3%.	$119.9 \times 1.083 = 129.9$
Add three patients from Nash and Wilson counties. This is ending census for OY 2.	$129.9 + 3 = 132.9$

Source: Tables in Sections C and Q, pages 19 and 70, respectively.

At the end of OY 1 (CY 2021), BMA Johnston projects to serve 122.9 in-center patients on 33 stations, for a utilization rate of 93.1%; and at the end of OY 2 (CY 2022) the facility is projected to serve 132.9 in-center patients on 33 stations, for a utilization rate of 100.6%.

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

- OY 1: 3.72 patients per station per week, or 93.1% utilization:  $122.9 / 33 = 3.72$ ;  $3.72 / 4 = 0.931$ .
- OY 2: 4.02 patients per station per week, or 100.6% utilization:  $132.9 \text{ patients} / 33 \text{ stations} = 4.02$ ;  $4.02 / 4 = 1.006$ .

The projected utilization of 3.7 patients per station per week at the end of OY 1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

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

- Johnston Dialysis was operating at 86.29% of capacity as of December 31, 2018, as reported in the July 2019 SDR.
- The applicant projects future in-center patient utilization based on historical utilization.
- The applicant projects growth of the Johnston County in-center patient population using the Johnston County AACR of 8.3%.
- Projected in-center utilization at the end of OY 1 exceeds the minimum of 3.2 patients per station per week required by 10A NCAC 14C .2203(b).

### Access

In Section C.7, page 22, the applicant states:

*“... Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.*

...

*Fresenius related facilities in North Carolina have historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for being an underserved person.”*

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



**Johnston Dialysis Projected Payor Mix, CY 2022**

<b>PAYOR SOURCE</b>	<b>% OF TOTAL</b>
Self Pay	2.91%
Insurance*	9.55%
Medicare*	57.56%
Medicaid*	15.18%
Medicare Commercial	12.15%
Miscellaneous (Incl. VA)	2.65%
<b>Total</b>	<b>100.00%</b>

\*Includes any managed care plans  
Totals may not sum due to rounding

The projected payor mix is reasonable and adequately supported.

**Conclusion**

The Agency reviewed the:

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

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

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

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

NA

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

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

CA

The applicant proposes to add one dialysis stations to Johnston Dialysis, for a total of 33 dialysis stations upon completion of this project and the following three projects:

- Project ID #J-11372-17 - Develop a new 10-station facility (FKC Selma) by relocating two dialysis stations from FMC Four Oaks, four from Johnston Dialysis and four from FMC New Hope Dialysis
- Project ID #J-11407-17 - add one station to Johnston Dialysis Center
- Project ID #J-11540-18 - relocate four stations from Zebulon Kidney Center to Johnston Dialysis Center

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

1. Maintain the status quo – the applicant states this was not a reasonable alternative because it fails to recognize the growth of the ESRD patient population residing in the service area of Johnston Dialysis. The applicant states the facility is well-utilized, and projects to serve 132.9 in-center patients at the end of OY 2.
2. Relocate stations from another BMA facility in Johnston County – the applicant states it considered relocating stations from one of its other dialysis facilities in Johnston County, as follows:
  - a. FMC Four Oaks – the applicant states this facility was operating at 73.86%, but Project ID #J-11372-17 authorized the relocation of two stations from that facility. Relocating additional stations out of this facility would not be appropriate.
  - b. Fresenius Medical Care Stallings Station – the applicant states utilization at this facility was 90.63% at the end of 2018. The applicant filed an application in September 2019 to add two stations to that facility. Relocating stations from Johnston Dialysis Center would not be appropriate.

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

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

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

## **Conclusion**

The Agency reviewed the:

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

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

- 1. Bio-Medical Applications of North Carolina, Inc. shall materially comply with all representations made in the certificate of need application.**
  - 2. Pursuant to the facility need determination in the July 2019 SDR, Bio-Medical Applications of North Carolina, Inc. shall develop no more than one additional dialysis station at Johnston Dialysis Center for a total of no more than 33 dialysis stations, which shall include any home hemodialysis training or isolation stations, upon completion of this project and Project ID #J-11372-17 (relocate 4 stations to FKC Selma), Project ID #J-11407-17 (add one station) and Project ID #J-11540-18 (relocate four stations from Zebulon Kidney Center).**
  - 3. Bio-Medical Applications of North Carolina, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

## C

The applicant proposes to add one dialysis station to Johnston Dialysis, an existing dialysis facility, for a total of 33 dialysis stations upon completion of this project and three additional projects.

## **Capital and Working Capital Costs**

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

Construction/Renovation	\$219,212
Architect / Engineering Fees	\$ 21,921
Non-Medical Equipment	\$ 35,000
Furniture	\$ 19,650
Contingency	\$ 36,170
<b>Total</b>	<b>\$331,953</b>

In Section Q, page 75, the applicant provides the assumptions used to project the capital cost.

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

**Availability of Funds**

In Section F.2, page 30, the applicant states that the capital cost will be funded as shown in the table below.

**SOURCES OF CAPITAL COST FINANCING**

TYPE	BIO-MEDICAL APPLICATIONS OF NORTH CAROLINA, INC.	TOTAL
Loans	0	0
Accumulated reserves or OE *	\$331,953	\$331,953
Bonds	0	0
Other (Specify)	0	0
<b>Total Financing</b>	<b>\$331,953</b>	<b>\$331,953</b>

\* OE = Owner's Equity

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

**Financial Feasibility**

The applicant provides pro forma financial statements for the first two full operating years following completion of the project. In Form F.2, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as summarized in the table below.

**BMA JOHNSTON PROJECTED REVENUE AND OPERATING EXPENSES**

	<b>OY 1 CY 2021</b>	<b>OY 2 CY 2022</b>
Total Treatments	17,509.62	18,926.06
Total Gross Revenue (charges)	\$110,153,010	\$119,063,873
Total Net Revenue	\$5,139,561	\$5,555,327
Average Net Revenue per Treatment	\$293.53	\$293.53
Total Operating Expenses (costs)	\$3,997,728	\$4,195,959
Average Operating Expense per Treatment	\$228.32	\$221.70
<b>Net Income / Profit (loss)</b>	<b>\$1,141,833</b>	<b>\$1,359,368</b>

Totals may not sum due to rounding by Project Analyst

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs, and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

**Conclusion**

The Agency reviewed the:

- application, and
- exhibits to the application.

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

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

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

**C**

BMA proposes to add one dialysis stations to Johnston Dialysis, for a total of 33 dialysis stations upon completion of this project and the following three projects:

- Project ID #J-11372-17 - Develop a new 10-station facility (FKC Selma) by relocating two dialysis stations from FMC Four Oaks, four from Johnston Dialysis and four from FMC New Hope Dialysis

- Project ID #J-11407-17 - add one station to Johnston Dialysis Center
- Project ID #J-11540-18 - relocate four stations from Zebulon Kidney Center to Johnston Dialysis Center

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

According to the July 2019 SDR, there are five existing and approved dialysis facilities in Johnston County, all of which are owned or operated by the applicant or a related entity, as follows:

**Johnston County Dialysis Facilities, July 2019 SDR (as of 12/31/18)**

FACILITY	# IN-CENTER PATIENTS	# STATIONS	% UTILIZATION
FMC Four Oaks	65	22	73.86%
FMC Stallings Station	87	24	90.63%
Johnston Dialysis Center	107	31	86.29%
Fresenius Kidney Care Selma	0	0	0.00%
Fresenius Kidney Care West Johnston	0	0	0.00%
<b>Total</b>	<b>259</b>	<b>77</b>	<b>84.1%</b>

On page 36, the applicant provides a table to illustrate the number of stations in Johnston County as of June 30, 2019, as shown below:

**Johnston County Dialysis Facilities as of June 30, 2019**

FACILITY	# IN-CENTER PATIENTS	# STATIONS	% UTILIZATION
FMC Four Oaks	69	22	78.41%
FMC Stallings Station	86	2486	89.58%
Johnston Dialysis Center	117	13	94.35%
Fresenius Kidney Care Selma	0	0	0.00%
Fresenius Kidney Care West Johnston	0	0	0.00%
<b>Total</b>	<b>272</b>	<b>77</b>	<b>88.3%</b>

Source: application page 36, using data from the ESRD Data Collection Forms submitted to the Agency

Per the July 2019 SDR, as of December 31, 2018, Fresenius related entities own and operate all of the existing dialysis facilities in Johnston County with a total of 77 certified stations. As stated by the applicant in Section G, page 36, utilization in two of the existing Johnston County facilities increased as of June 30, 2019, as shown in the data submitted to the Agency on the ESRD Data Collection Forms in August 2019.

In Section G, page 37, the applicant explains why it believes the proposal would not result in the unnecessary duplication of existing or approved dialysis services in Johnston County based on the utilization as of June 30, 2019. The applicant states:

*“This is an application to add one station to BMA Johnston.*

*The July 2019 SDR does report a deficit of 12 stations in Johnston County. Additional stations are needed by the dialysis patient population of the county.*

*Approval of this application does not cause unnecessary duplication of services, but will ensure an adequate inventory of dialysis stations exists fo [sic] the ESRD patient population of the county.”*

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

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

### **Conclusion**

The Agency reviewed the:

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

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

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

### C

In Form H Staffing, in Section Q, page 88, the applicant provides a table illustrating current and projected OY 2 staffing in full time equivalents (FTEs) for Johnston Dialysis, as summarized below.

**Johnston Dialysis Current and Projected Staffing**

POSITION	FTE POSITIONS AS OF 6/30/19	FTE POSITIONS OY 1 (CY 2021)	FTE POSITIONS OY 2 (CY 2022)
FMC Clinic Manager	1.00	1.00	1.00
Registered Nurses	4.75	4.75	4.75
LPNs	1.00	1.00	1.00
Technicians	11.00	11.00	11.00
Dietician	1.00	1.00	1.00
Social Worker	1.00	1.00	1.00
Equipment Technician	1.00	1.00	1.00
Administration	1.00	1.00	1.00
FMC Director of Operations	0.15	0.15	0.15
In-Service	0.20	0.20	0.20
Chief Technician	0.20	0.20	0.20
<b>Total</b>	<b>22.30</b>	<b>22.30</b>	<b>22.30</b>

Source: Section Q Form H

The applicant does not project to hire any new FTE positions following the addition of one station as proposed in this application. Adequate costs for the current health manpower and management positions as shown by the applicant are budgeted in Form F.4 Operating Costs. In Section H, page 38, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. Exhibit H contains documentation of its continuing education programs. In Section H.4, page 39, the applicant identifies the current medical director for the facility as Dr. Fan. In Exhibit H-4, the applicant provides a letter from Dr. Fan confirming his intent to continue to serve as medical director for the proposed services.

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

**Conclusion**

The Agency reviewed the:

- application, and
- exhibits to the application.

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

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



C

In Section I, page 41, the applicant states that the following ancillary and support services are necessary for the proposed services, and explains how each ancillary and support service is made available:

JOHNSTON DIALYSIS ANCILLARY AND SUPPORT SERVICES	
SERVICES	PROVIDER
Self-care training	Referred to FMC Stallings Station
Home training Home Hemodialysis Peritoneal Dialysis Accessible follow-up program	Referred to FMC Stallings Station
Psychological counseling	Referral to Johnston Health or WakeMed
Isolation – hepatitis	Provided on site by applicant
Nutritional counseling	Provided on site by applicant
Social Work services	Provided on site by applicant
Acute dialysis in an acute care setting	Referral to UNC Healthcare
Emergency care	Provided by facility staff until ambulance arrives*
Blood bank services	Referral to UNC Healthcare*
Diagnostic and evaluation services	Referral to Johnston Health
X-ray services	Referral to Johnston Health
Laboratory services	Provided on site by applicant
Pediatric nephrology	Referral to UNC Healthcare
Vascular surgery	Referral to Rex Vascular, Wake Vascular or Raleigh Access Center
Transplantation services	Referral to UNC, Johnston Health or WakeMed
Vocational rehabilitation & Counseling	Referral to Johnston County Mental Health
Transportation	Referral to Amedisys Home Health

Source: Application page 41

\*In the table submitted by the applicant on page 41, these two services appear to have been transposed.

In Section I, page 41, the applicant describes its existing and proposed relationships with other local health care and social service providers. In Exhibit I, the applicant provides supporting documentation for established relationships with local health care providers and for referrals.

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

**Conclusion**

The Agency reviewed the:

- application, and
- exhibits to the application.

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

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
  - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
  - (iii) would cost no more than if the services were provided by the HMO; and
  - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C

The applicant proposes to add one dialysis station to Johnston Dialysis for a total of 33 dialysis stations upon project completion.

In Section K, page 44, the applicant states that the project renovating 1,000 square feet of existing space. Line drawings are provided in Exhibit K.2.

On page 45, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal, and why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

On page 45, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

(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 49, the applicant provides the historical payor mix during CY 2018 for its existing services at Johnston Dialysis, as summarized in the table below.

**JOHNSTON DIALYSIS  
 HISTORICAL PAYOR MIX CY 2018**

PAYOR SOURCE	% OF TOTAL
Self pay	2.91%
Insurance*	9.55%
Medicare*	57.56%
Medicaid*	15.18%
Medicare Commercial	12.15%
Other (VA)	2.65%
<b>Total</b>	<b>100.00%</b>

Numbers may not sum due to rounding

In Section L.1(a), page 48, the applicant compares demographic information on Johnston Dialysis patients and the service area population during CY 2018, as summarized below:

	PERCENTAGE OF TOTAL JOHNSTON DIALYSIS PATIENTS SERVED DURING THE LAST FULL OY	PERCENTAGE OF THE POPULATION OF THE SERVICE AREA
Female	46.2%	51.3%
Male	53.8%	48.7%
Unknown		
64 and Younger	51.3%	88.4%
65 and Older	48.7%	11.6%
American Indian	0.0%	0.8%
Asian	59.5%	7.5%
Black or African-American	0.0%	21.0%
Native Hawaiian or Pacific Islander	24.8%	0.1%
White or Caucasian	13.2%	59.8%
Other Race	59.5%	10.8%
Declined / Unavailable	1.7%	

\* The percentages can be found online using the United States Census Bureau's QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>. Just enter in the name of the county.

**Conclusion**

The Agency reviewed the:

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

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's

service area which is medically underserved. Therefore, the application is conforming to this criterion.

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

C

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, the applicant states in Section L, page 49, that it has no obligation in any of its facilities to provide uncompensated care, community service, or access by minorities or handicapped persons under any federal regulations.

In Section L, page 50, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

### **Conclusion**

The Agency reviewed the:

- application, and
- exhibits to the application.

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

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

C

In Section L, page 50, the applicant projects the following payor mix for the proposed services during the second full operating year following completion of the project, as summarized in the table below.

**JOHNSTON DIALYSIS  
PROJECTED PAYOR MIX CY 2022**

<b>PAYOR SOURCE</b>	<b>% OF TOTAL</b>
Self pay	2.91%
Insurance*	9.55%
Medicare*	57.56%
Medicaid*	15.18%
Medicare Commercial	12.15%
Other (VA)	2.65%
<b>Total</b>	<b>100.00%</b>

Numbers may not sum due to rounding

As shown in the table above, during the second year of operation, the applicant projects that 2.91% of total in-center services will be provided to self-pay patients, 69.71% to Medicare patients (includes Medicare and Medicare/Commercial), and 15.18% to Medicaid patients.

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

**Conclusion**

The Agency reviewed the:

- application, and
- exhibits to the application.

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

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

C

In Section L, page 51, the applicant adequately describes the range of means by which patients will have access to the proposed services.

**Conclusion**

The Agency reviewed the:

- application, and

- exhibits to the application.

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

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

C

In Section M, page 53, 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-2.

**Conclusion**

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.  
(16) Repealed effective July 1, 1987.  
(17) Repealed effective July 1, 1987.  
(18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

BMA proposes to add one dialysis stations to Johnston Dialysis, for a total of 33 dialysis stations upon completion of this project and the following three projects:

- Project ID #J-11372-17 - Develop a new 10-station facility (FKC Selma) by relocating two dialysis stations from FMC Four Oaks, four from Johnston Dialysis and four from FMC New Hope Dialysis

- Project ID #J-11407-17 - add one station to Johnston Dialysis Center
- Project ID #J-11540-18 - relocate four stations from Zebulon Kidney Center to Johnston Dialysis Center

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

According to the July 2019 SDR, there are five existing and approved dialysis facilities in Johnston County, all of which are owned or operated by the applicant or a related entity, as follows:

**Johnston County Dialysis Facilities, July 2019 SDR (as of 12/31/18)**

FACILITY	# IN-CENTER PATIENTS	# STATIONS	% UTILIZATION
FMC Four Oaks	65	22	73.86%
FMC Stallings Station	87	24	90.63%
Johnston Dialysis Center	107	31	86.29%
Fresenius Kidney Care Selma	0	0	0.00%
Fresenius Kidney Care West Johnston	0	0	0.00%
<b>Total</b>	<b>259</b>	<b>77</b>	

In Section N, pages 54 - 56, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality, and access to the proposed services. The applicant states:

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

*There are currently three Fresenius related dialysis facilities within Johnston County. With this application; BMA has approved CONs to develop two additional facilities. BMA is also aware that DaVita has filed to develop a new facility in Clayton. [sic]*

*BMA seeks the opportunity to continue providing dialysis care and treatment to the patients of the area who have expressed their desire to receive dialysis care and treatment at BMA Johnston.*

...



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

...

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

...

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

...

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

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

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

### **Conclusion**

The Agency reviewed the:

- application, and
- exhibits to the application.

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

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

C

In Section Q Form A Facilities, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies 127 dialysis facilities owned, operated, or managed by the applicant or a related entity located in North Carolina.

In Section O, page 60, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care that resulted in a finding of “*Immediate Jeopardy*” occurred in any of these facilities. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all Fresenius facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The application is conforming to all applicable criteria, as discussed below.

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

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

-NA- Johnston Dialysis Center is an existing facility.

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

- C- In Section C, page 20 and Section Q Form C, page 68, the applicant projects that Johnston Dialysis will serve 122.9 in-center patients on 33 stations, or a rate of 3.72 patients per station per week, as of the end of the first operating year following project completion. This exceeds the minimum performance standard of 3.2 patient per station per week. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- (c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section C, pages 18 - 20 and Section Q, pages 69 - 71, the applicant provides the assumptions and methodology it used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.