

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: July 20, 2018

Findings Date: July 20, 2018

Project Analyst: Bernetta Thorne-Williams

Team Leader: Gloria Hale

Assistant Chief: Lisa Pittman

Project ID #: J-11473-18

Facility: Fresenius Medical Care Stallings Station

FID #: 030941

County: Johnston

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

Project: Add four dialysis stations for a total of 18 dialysis stations upon completion of this project and Project I.D. # J-11435-17 (relocate 10 stations to FKC West Johnston)

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §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. (BMA) d/b/a Fresenius Medical Care Stallings Station (FMC Stallings Station) proposes to add four dialysis stations upon completion of this project and Project I.D. # J-11435-17 (relocate 10 stations to FKC West Johnston) for a total of 18 dialysis stations at FMC Stallings Station.

#### **Need Determination**

The 2018 State Medical Facilities Plan (2018 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table

D in the January 2018 Semiannual Dialysis Report (SDR) the county need methodology shows there is a deficit of two dialysis stations in Johnston County. Therefore, the January 2018 SDR does not indicate a need for additional stations in Johnston County based on the county need methodology, which states that the county deficit must be ten or greater to establish a need for additional stations. 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 FMC Stallings Station in the January 2018 SDR is 3.4583 patients per station per week, or 86.46% ( $3.4583 / 4 \text{ patients per station} = 0.86457$ ). This utilization rate was calculated based on 83 in-center dialysis patients and 24 certified dialysis stations ( $83 \text{ patients} / 24 \text{ stations} = 3.4583 \text{ patients per station per week}$ ).

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

<b>APRIL 1 REVIEW-JANUARY SDR</b>		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/17		86.46%
Certified Stations		24
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>24</b>
In-Center Patients as of 6/30/17 (SDR2)		83
In-Center Patients as of 12/31/16 (SDR1)		78
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 12/31/16	0.1282
(ii)	Divide the result of step (i) by 12	0.0107
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/17 until 12/31/17)	0.0641
(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	88.3205
(v)	Divide the result of step (iv) by 3.2 patients per station	27.6002
	and subtract the number of certified and pending stations to determine the number of stations needed	<b>4</b>

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

### **Policies**

Policy GEN-3 on page 33 of the 2018 SMFP is applicable to this review because the facility need methodology is applicable to this review. Policy GEN-3 states:

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

### **Promote Safety and Quality**

The applicant describes how it believes the proposed project would promote safety and quality in Section B.4, page 8, Section K.1(g), page 42, Section N.1, page 51, Section O, pages 53-57, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

### **Promote Equitable Access**

The applicant describes how it believes the proposed project would promote equitable access in Section B.4, pages 8-9, Section C, pages 13-16, Section L, pages 45-46, Section N.1, page 51, 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 9-10, Section C.1, pages 13-15, Section F, pages 23-29, Section K, pages 40-42, Section N, page 51, 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 also consistent with Policy GEN-3.

## **Conclusion**

The Agency reviewed the:

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

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

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

## C

Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a Fresenius Medical Care Stallings Station (FMC Stallings Station) proposes to add four dialysis stations upon completion of this project and Project I.D. # J-11435-17 (relocate 10 stations to FKC West Johnston) for a total of 18 dialysis stations at FMC Stallings Station.

## **Patient Origin**

On page 365, the 2018 SMFP defines the service area for dialysis stations as, “*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area is Johnston County. Facilities may serve residents of counties not included in their service area. In Section C.1, page 13 and Section C.8, page 19, the applicant provides the projected and historical patient origin for FMC Stallings Station in-center (IC), home hemodialysis (HHD) and peritoneal dialysis (PD) patients, as illustrated in the tables below.

<b>FMC STALLINGS STATION as of December 31, 2017</b>				
<b>County of Residence</b>	<b>IC Patients</b>	<b>HHD Patients</b>	<b>PD Patients</b>	<b>County Patients as a Percent Of Total</b>
Johnson	79	6	12	90.7%
Harnett	0	0	2	1.9%
Wake	6	0	2	7.5%
<b>TOTAL</b>	<b>85</b>	<b>6</b>	<b>16</b>	<b>100.0%</b>

<b>FMC STALLINGS STATION</b>								
	<b>OPERATING YEAR 1 CY2020</b>			<b>OPERATING YEAR 2 CY2021</b>			<b>COUNTY PATIENTS AS A PERCENT OF TOTAL</b>	
	<b>IN- CENTER</b>	<b>HHD PATIENTS</b>	<b>PD PATIENTS</b>	<b>IN- CENTER</b>	<b>HHD PATIENTS</b>	<b>PD PATIENTS</b>	<b>YEAR 1</b>	<b>YEAR 2</b>
Johnston	83.2	7.2	14.4	88.4	7.7	15.3	93.7%	94.1%
Harnett	0.0	0.0	2.0	0.0	0.0	2.0	1.8%	1.7%
Wake	3.0	0.0	2.0	3.0	0.0	2.0	4.5%	4.2%
<b>TOTAL</b>	<b>86.2</b>	<b>7.2</b>	<b>18.4</b>	<b>91.4</b>	<b>7.7</b>	<b>19.3</b>	<b>100.0%</b>	<b>100.0%</b>

In the table on page 13, the applicant rounds down to the nearest whole patient for calendar year (CY) 1 and 2, therefore, the applicant projects to serve 86 in-center patients in CY1 and 91 in-center patients in CY2. In Section C, pages 13-15, the applicant provides the assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported.

**Analysis of Need**

In Section C, pages 13-15, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. In Section B, page 6, the applicant states the application is filed pursuant to the facility need methodology in the 2018 SMFP utilizing data from the January 2018 SDR.

On pages 13-14, the applicant states:

- The applicant begins the projections for the future patient population of FMC Stallings Station by using the ending in-center patient census of 79 patients for Johnston County, as of December 31, 2017.
- The applicant uses the Five-Year Average Annual Change Rate (AACR) for Johnston County which is 6.3% to project the Johnston County patient population forward. This utilization is confirmed through the facility need methodology on page 13.

- In Project I.D. # J-11435-17, BMA was approved to relocate 10 dialysis stations from FMC Stallings Station to develop a new facility, Fresenius Kidney Care West Johnston (FKC West Johnston). The applicant projected that 11 Johnston County patients dialyzing at FMC Stallings Station would transfer their care to the new facility. BMA subtracts 11 Johnston County patients from its Johnston County patient census as of December 31, 2019.
- BMA projects that three of the six Wake County patients dialyzing at FMC Stallings Station will also transfer their care to FKC Johnston County upon project completion. The applicant does not project an increase in the patient population for Wake County.
- Operating Year 1 (OY1) = Calendar Year (CY) 2020  
Operating Year 2 (OY2) = Calendar Year (CY) 2021

The information is reasonable and adequately supported for the following reasons:

- the applicant begins its projections of the patient population to be served with the existing patient census of FMC Stallings Station on December 31, 2017;
- the applicant grows the Johnston County patient population by the January 2018 SDR Johnston County five-year AACR of 6.3% and holds utilization constant for patients from outside Johnston County, and,
- the utilization rate of the in-center patients projected to be dialyzing at FMC Stallings Station by the end of the first year is above the 3.2 minimum standard of patients per station per week.

#### Projected Utilization

In Section C, page 14, the applicant provided the methodology used to project in-center utilization, as illustrated in the following table,

FMC Stallings Station  
J-11473-18  
Page 7

Begin with Johnston County patients dialyzing at FMC Stallings Station as of December 31, 2017.	79
Project the Johnston County patient population forward one year to December 31, 2018 using the Five-Year Average Annual Change Rate for Johnston County of 6.3%	$79 \times 1.063 = 84$
Project the Johnston County patient population forward one year to December 31, 2019 using the Five-Year Average Annual Change Rate for Johnston County of 6.3%.	$84 \times 1.063 = 89.3$
Subtract 11 Johnston County patients projected to transfer their care to FKC West Johnston.	$89.3 - 11 = 78.3$
Project the Johnston County patient population forward one year to December 31, 2020 using the Five-Year Average Annual Change Rate for Johnston County of 6.3%.	$78.3 \times 1.063 = 83.2$
<b>OY1:</b> Add in three patients from Wake County. This is the projected census for OY 1.	$83.2 + 3 = 86.2$
Project the Johnston County population forward one year to December 31, 2021 using the Five-Year Average Annual Change Rate for Johnston County of 6.3%.	$83.2 \times 1.063 = 88.4$
<b>OY2:</b> Add three patients from Wake County. This is the projected census for OY 2.	$88.4 + 3 = 91.4$

The applicant provides the assumptions for the projected in-center utilization on pages 13-14, as summarized below:

- Beginning census, December 31, 2017, is as listed in the ESRD Data Collection Forms submitted to DHSR Healthcare Planning in February 2018.
- OY1 is the period from January 1 through December 31, 2020.
- OY2 is the period from January 1 through December 31, 2021.
- The applicant includes a list of names in Exhibit C.1 of patients currently dialyzing at FMC Stallings Station who have expressed a willingness to consider transferring their dialysis care to FKC West Johnston.
- The Johnston County patient census will grow at the Johnston County AACR of 6.3%, as reported in the January 2018 SDR, and the Wake County census will be held constant.

In Section C.2, page 16, the applicant states:

*“In this application, BMA has projected a patient population of 86.2 rounded down to 86 in-center patients, to be dialyzing at the FMC Stallings Station facility at the end of the first year. Failure to add the stations will lead to higher utilization rates at the facility. Utilization by 86 patients on 28 [sic] dialysis stations is calculated to be 4.7778 patients per station, or 119.44% utilization.”*

It is assumed that the applicant made a typographical error on page 16 in reporting that 86 patients dialyzing on 28 stations would equate to 4.77 patients and 119.44% utilization [ $86 / 28 = 3.07 / 4 = 0.76.785$  or 76.79 %]. However, 86 patients divided by 18 stations (the number of stations the

applicant projects to have following completion of this project and Project I.D. # # J-11435-17) would equate to 4.77 patients and 119.44% utilization [ $86 / 18 = 4.777 / 4 = 1.1944$  or 119.44%]. Without the addition of the four stations, as proposed in the application, the applicant would have a utilization of 153.57% which is based on 86 patients dialyzing on 14 stations [ $86 / 14 = 6.14 / 4 = 1.5357$  or 153.57%]. Therefore, the applicant demonstrates a need for four additional stations pursuant to the facility need methodology on page 6 of the application.

On page 14, the applicant rounds down to the nearest whole patient for calendar year (CY) 1 and 2, therefore, the applicant projects to serve 86 in-center patients in CY1 and 91 in-center patients in CY2. Thus, the applicant projects that FMC Stallings Station will have a utilization rate of 85.4% or 4.77 patients per station per week (86 patients / 18 stations =  $4.777 / 4 = 1.1944$  or 119.44%) in CY1. The projected utilization of 4.77 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).

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

- the applicant begins its utilization projection with the existing patients of FMC Stallings Station,
- the applicant grows the Johnston County patient population by the January 2018 SDR Johnston County AACR and holds the patient population from outside Johnston County constant, and
- the resulting utilization rate at FMC Stallings Station by the end of the first year is above the minimum standard of 3.2 patients per station per week.

#### Home Hemodialysis and Peritoneal Dialysis

On page 15, the applicant provides its methodology for growth within its HHD and PD patient population. The applicant projects to serve 7 HHD patients in OY1 and 2, 18 PD patients in OY1 and 19 PD patients in OY2.

#### Access

In Section L.1(a), pages 45-46, the applicant states that each of BMA's 112 facilities in 48 North Carolina counties has a patient population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, or other traditionally underserved persons regardless of their ability to pay. In Section L.7, page 49, the applicant provides the historical payor mix for calendar year (CY) 2017 for FMC Stallings Station, as illustrated below.



Payment Source	Percent of Total Patients	Percent of In-Center Patients	Percent of HHD Patients	Percent of PD Patients
Self Pay/ Indigent/ Charity	0.84%	0.84%	0.79%	0.79%
Medicare	69.75%	69.97%	70.87%	70.87%
Medicaid	4.20%	4.25%	3.27%	3.27%
Commercial Insurance	8.40%	7.38%	11.45%	11.45%
Medicare / Commercial	15.13%	15.14%	13.62%	13.62%
Misc. (VA)	1.68%	2.42%	0.00%	0.00%
<b>Total</b>	<b>100.00%</b>	<b>100.00%</b>	<b>100.00%</b>	<b>100.00%</b>

As illustrated in the table above, in CY2017 89.08% of all FMC Stallings Station patients were Medicare or Medicaid recipients. On page 46, the applicant states it future payor mix in project year (PY) 2 is based on the facility's experience throughout CY2017.

The projected payor mix is reasonable and adequately supported.

### **Conclusion**

The Agency reviewed the:

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

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

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

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

NA

The applicant does not propose to reduce, eliminate nor relocate a facility or services as a part of this review. 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 four dialysis stations for a total of 18 certified dialysis stations upon completion of this project and Project I.D. # J-11435-17.

In Section E.1, page 22, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the status quo - The applicant states that maintaining the status quo is not an effective alternative because the utilization at FMC Stallings Station will be greater than 80% by the end of OY1. This could force the facility to operate a third shift six days of the week. Therefore, this alternative was rejected.
- Relocate stations from Johnston Dialysis Center or FMC Four Oaks – The applicant reports that both facilities are well utilized. The applicant states on page 22, that FMC Four Oaks operates above 70% utilization consistently. The January 2018 SDR (utilization as of June 30, 2017) reports a utilization rate of 73.86% for FMC Four Oaks and a utilization rate of 95.0% for Johnston Dialysis Center. The applicant reports that FMC Four Oaks has been reserved to relieve capacity at other BMA facilities in Johnston and Harnett counties. Additionally, the applicant states that two stations are being relocated from FMC Four Oaks to the new FKC Selma facility. Therefore, this alternative was rejected.

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

- the facility is operating above 80% capacity,
- the applicant's need methodology indicates a need for additional stations at the facility,
- to maintain the status quo does not address the need for additional stations at the facility and would result in higher utilization and potentially require the addition of a third shift six days a week, and
- applying for less than four stations pursuant to the facility need methodology would result in a higher utilization than 4.7 patients per station.

#### **Conclusion**

The Agency reviewed the:

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

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

- 1. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Stallings Station shall materially comply with all representations made in the certificate of need application.**
  - 2. Pursuant to the facility need determination in the January 2018 SDR, Bio-Medical Applications of North Carolina, Inc. shall develop no more than four additional dialysis stations for a total of no more than 18 certified stations at FMC Stallings Station which shall include any home hemodialysis training or isolation stations upon completion of this project and Project I.D. # J-11435-17.**
  - 3. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Stallings Station shall install plumbing and electrical wiring through the walls for no more than four additional dialysis stations, which shall include any isolation or home hemodialysis training stations.**
  - 4. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Stallings Station 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 four dialysis stations for a total of 18 certified dialysis stations upon completion of this project and Project I.D. # J-11435-17.

### **Capital and Working Capital Costs**

In Section F.1, page 23, the applicant projects no capital cost for the proposed project. In Section F.10, page 26, the applicant projects no start-up expenses or initial operating expenses because FMC Stallings Station is an existing operational facility.

### **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 revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

	Operating Year 1 CY2019	Operating Year 2 CY2020
Total Treatments	12,300	13,041
Total Gross Revenues (Charges)	\$63,823,952	\$66,779,060
Total Net Revenue	\$5,129,484	\$5,364,285
Average Net Revenue per Treatment	\$417.03	\$411.34
Total Operating Expenses (Costs)	\$4,063,567	\$4,212,717
Average Operating Expense per Treatment	\$330.37	\$323.04
Net Income	\$1,065,916	\$1,151,568

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

### **Conclusion**

The Agency reviewed the:

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

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

- The applicant adequately demonstrates 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

The applicant proposes to add four dialysis stations for a total of 18 certified dialysis stations upon completion of this project and Project I.D. # J-11435-17.

On page 365, the 2018 SMFP defines the service area for dialysis stations as *“the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.”* Thus, the service area is Johnston County. Facilities may serve residents of counties not included in their service area.

According to the January 2018 SDR, there are currently three operational dialysis facilities and two facilities under development in Johnston County, all of which are operated by BMA, as illustrated below. One proposed facility, Clayton Dialysis, was not approved.

<b>JOHNSTON COUNTY DIALYSIS FACILITIES EXISTING &amp; APPROVED CERTIFIED STATIONS &amp; UTILIZATION as of June 30, 2017</b>				
<b>Dialysis Facility</b>	<b>Certified Stations 6/30/17</b>	<b># In-center Patients</b>	<b>Percent Utilization</b>	<b>Patients per Station</b>
FMC Four Oaks	22	65	73.86%	2.9545
FMC Stallings Station	24	83	86.46%	3.4583
FKC Selma*				
FKC West Johnston*				
Clayton Dialysis**				
Johnston Dialysis Center	25	95	95.00%	3.8000
<b>Total</b>	<b>71</b>	<b>243</b>	<b>85.56%</b>	<b>3.4225</b>

Source: January 2018 SDR

\*Approved, but not operational.

\*\*Clayton Dialysis, a proposed new site listed in the January 2018 SDR was not approved.

As shown in the table above, FMC Stallings Station operated with a utilization rate of 86.46%. With regard to the facilities under development, on page 31 the applicant states, *“Project ID # J-11372-17, to develop the FKC Selma facility by relocating two dialysis stations from FMC Four Oaks, four dialysis stations from (BMA) Johnston Dialysis Center, and four dialysis stations from FMC New Hope (in Wake County) ... is scheduled for completion as of December 31, 2018.”*

BMA was approved on April 5, 2018 to develop FKC West Johnston by relocation ten dialysis stations from FMC Stallings Station.

In Section G, page 31, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Johnston County. The applicant states, *“After considering plans for the two new facilities, the patient residence locations across the county and the growth of the ESRD patient population within Johnston County, BMA believes these stations are necessary, cost effective and will not unnecessarily duplicate existing health services.”*

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services because the applicant adequately demonstrates that the proposed addition of four dialysis stations at FMC Stallings Station is needed in addition to the existing or approved dialysis stations.

**Conclusion**

The Agency reviewed the:

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

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

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

C

In Section H, page 32, the applicant provides current and projected staffing for the proposed services, as illustrated in the following table.

<b>POSITION</b>	<b>CURRENT # FTEs</b>	<b>PROJECTED # FTEs OY2</b>
Registered Nurse	3.00	4.00
Home Training Nurse	3.00	3.00
Technician (PCT))	8.00	10.00
Dietician	1.00	1.00
Social Worker	1.00	1.00
Clinical Manager	1.00	1.00
Admin. (FMC Dir. Ops)	0.20	0.20
In-Service	0.20	0.20
Clerical	1.50	1.50
Chief Tech	0.20	0.20
Equipment Tech	0.80	0.80
<b>Total</b>	<b>19.90</b>	<b>22.90</b>

The assumptions and methodology used to project staffing are provided in Section H and Section R. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, pages 61-62, which is found in Section R. In Section H, pages 32-33, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Exhibit I.5, the applicant provides a letter from the medical

director indicating her interest in continuing to serve as the medical director of FMC Stallings Station.

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

### **Conclusion**

The Agency reviewed the:

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

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

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

### C

In Section I, page 35, the applicant provides a list of the necessary ancillary and support services, as illustrated below.

<b>FMC Stallings Station Ancillary and Support Services</b>	
<b>Services</b>	<b>Provider</b>
In-center dialysis/maintenance	FMC Stallings Station (on site)
Self-care training (in-center)	FMC Stallings Station (on site)
Home training HH PD Accessible follow-up program	FMC Stallings Station (on site)
Psychological counseling	Johnston County Mental Health
Isolation – hepatitis	FMC Stallings Station (on site)
Nutritional counseling	FMC Stallings Station (on site)
Social Work services	FMC Stallings Station (on site)
Acute dialysis in an acute care setting	Wake Med Raleigh or Johnston Memorial Hospital
Emergency care	Wake Med Raleigh or Johnston Memorial Hospital
Blood bank services	Rex Hospital, Raleigh
Diagnostic and evaluation services	Johnston Health, Clayton
X-ray services	Johnston Health, Clayton
Laboratory services	Spectra
Pediatric nephrology	UNC Hospitals
Vascular surgery	Raleigh Access Center, Triangle Access Center, Rex Vascular
Transplantation services	UNC Hospitals
Vocational rehabilitation & counseling	Vocational Rehab. of Johnson County
Transportation	Johnston Coordinated Transportation (JCATS)

The applicant provides supporting documentation in Exhibit I.2-5. Exhibits I-2 through I-4, respectively, contain copies of agreements for Spectra for laboratories services, WakeMed for transfer agreement and Duke University Medical Center for transplant services.

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

### **Conclusion**

The Agency reviewed the:

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

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



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

NA

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

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates:

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

NA

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

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

persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

The applicant does not propose to construct new space nor renovate the existing space. Therefore, Criterion (12) is not applicable to this review.

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

- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L.7, page 49, the applicant provides the historical payor mix during January 1 to December 31, 2017 for the proposed services, as shown in the table below.

Payment Source	Percent of Total Patients	Percent of In-Center Patients	Percent of HHD Patients	Percent of PD Patients
Self Pay/ Indigent/ Charity	0.84%	0.84%	0.79%	0.79%
Medicare	69.75%	69.97%	70.87%	70.87%
Medicaid	4.20%	4.25%	3.27%	3.27%
Commercial Insurance	8.40%	7.38%	11.45%	11.45%
Medicare / Commercial	15.13%	15.14%	13.62%	13.62%
Misc. (VA)	1.68%	2.42%	0.00%	0.00%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</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 the applicant's service area.

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2016 Estimate	2016 Estimate	2016 Estimate	2016 Estimate	2015 Estimate	2011-2015	2015 Estimate
Johnston	13%	51%	31%	13%	10%	14%
Statewide	16%	51%	37%	16%	10%	13%

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

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

\*\*"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2016) refers to the final year of the series (2010 thru 2016). Different vintage years of estimates are not comparable."

The IPRO SA Network 6 provides prevalence data on dialysis patients by age, race, and gender in its 2015 annual report, pages 27-28<sup>1</sup>. In 2015, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 67% were non-Caucasian and 45% were female. (IPRO SA Network 6). However, a direct comparison to the applicant's current payor mix would be of little value because the population data by age, race, or gender does not include information on the number of elderly, minorities, women or handicapped persons utilizing health services.

### Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the 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

<sup>1</sup>[http://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/05/2015\\_NW-6\\_Annual-Report\\_Final-11-29-2016.pdf](http://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/05/2015_NW-6_Annual-Report_Final-11-29-2016.pdf)

assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, pages 47-48, the applicant states:

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

In Section L, page 48, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

**Conclusion**

The Agency reviewed the:

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

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

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

C

In Section L, page 46, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

**Projected Payor Mix OY2**

Payment Source	Percent of Total Patients	Percent of In-Center Patients	Percent of HHD Patients	Percent of PD Patients
Self Pay/ Indigent/ Charity	0.84%	0.84%	0.79%	0.79%
Medicare	69.75%	69.97%	70.87%	70.87%
Medicaid	4.20%	4.25%	3.27%	3.27%
Commercial Insurance	8.40%	7.38%	11.45%	11.45%
Medicare / Commercial	15.13%	15.14%	13.62%	13.62%
Misc. (VA)	1.68%	2.42%	0.00%	0.00%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>

As shown in the table above, during the second full fiscal year of operation, the applicant projects the same payor source as CY2017 which consist of 84.88% Medicare patients (includes Medicare and Medicare/Commercial) and 4.20% Medicaid patients.

On page 46, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical utilization at FMC Stallings Station.

**Conclusion**

The Agency reviewed the:

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

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

- (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 48, the applicant adequately describes the range of means by which patients will have access to the proposed services

The Agency reviewed the:

- Application

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

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

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

C

In Section M, page 50, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.1.

**Conclusion**

The Agency reviewed the:

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

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

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

C

The applicant proposes to add four dialysis stations for a total of 18 certified dialysis stations upon completion of this project and Project I.D. # J-11435-17.

On page 365, the 2018 SMFP defines the service area for dialysis stations as “*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area is Johnston County. Facilities may serve residents of counties not included in their service area.

According to the January 2018 SDR, there are currently three operational dialysis facilities and two facilities under development in Johnston County, all of which are operated by BMA, as illustrated below. One proposed facility, Clayton Dialysis, was not approved.

<b>JOHNSTON COUNTY DIALYSIS FACILITIES EXISTING &amp; APPROVED CERTIFIED STATIONS &amp; UTILIZATION as of June 30, 2017</b>				
<b>Dialysis Facility</b>	<b>Certified Stations 6/30/17</b>	<b># In-center Patients</b>	<b>Percent Utilization</b>	<b>Patients per Station</b>
FMC Four Oaks	22	65	73.86%	2.9545
FMC Stallings Station	24	83	86.46%	3.4583
FKC Selma*				
FKC West Johnston*				
Johnston Dialysis Center	25	95	95.00%	3.8000
<b>Total</b>	<b>71</b>	<b>243</b>	<b>85.56%</b>	<b>3.4225</b>

Source: January 2018 SDR

\*Approved, but not operational.

\*\*Clayton Dialysis, a proposed new site listed in the January 2018 SDR was not approved.

As shown in the table above, FMC Stallings Station operated with a utilization rate of 86.46%. With regard to the facilities under development, on page 31 the applicant states, “*Project ID # J-11372-17, to develop the FKC Selma facility by relocating two dialysis stations from FMC Four Oaks, four dialysis stations from (BMA) Johnston Dialysis Center, and four dialysis stations from FMC New Hope (in Wake County) ... is scheduled for completion as of December 31, 2018.*”

BMA was approved on April 5, 2018 to develop FKC West Johnston by relocation ten dialysis stations from FMC Stallings Station.

BMA is the only provider of dialysis services in Johnston County. In Section N.1, page 51, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 51, 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 FMC Stallings Station 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 6.3% as published within the January 2018 SDR.”*

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

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

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information 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.

(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 A.11, page 4, the applicant states that BMA is a wholly owned subsidiary of Fresenius Medical Care Holdings, Inc. In Exhibit A.4, the applicant provides a list of its affiliates.

In Section O, pages 53-57, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in one of these facilities (BMA East Rocky Mount). The applicant states that all of the problems have been corrected as documented in Exhibit O-3. After reviewing and considering information provided by the applicant and considering the quality of care provided at all facilities, including those related or affiliated with the applicant, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.



(21) Repealed effective 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- FMC Stallings Station 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 13-16, the applicant demonstrates that FMC Stallings Station will serve a total of 86 in-center patients at the end of OY1 for a utilization rate of 119.44% or 4.7 patients per station per week (86 patients / 18 stations = 4.7 / 4 = 1.1944 or 119.44%). 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 13 -16, 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.