

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: October 29, 2018

Findings Date: October 29, 2018

Project Analyst: Bernetta Thorne-Williams

Team Leader: Gloria Hale

Project ID #: J-11540-18

Facility: Johnston Dialysis Center

FID #: 944566

County: Johnston

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

Project: Relocate four dialysis stations from Zebulon Kidney Center to Johnston Dialysis Center for a total of 32 dialysis stations upon completion of this project, Project I.D. # J-11372-17 (develop a new 10-station dialysis facility by relocating two dialysis stations from FMC Four Oaks, four stations from Johnston Dialysis Center and four stations from FMC Hope Dialysis) and Project I.D. # J-11407-17 (add one dialysis station to Johnston Dialysis Center)

### 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 Johnston Dialysis Center proposes to relocate four dialysis stations from Zebulon Kidney Center to Johnston Dialysis Center for a total of 32 dialysis stations upon completion of this project, Project I.D. # J-11372-17 (develop a new 10-station dialysis facility by relocating two dialysis stations from FMC Four

Oaks, four stations from Johnston Dialysis Center and four stations from FMC Hope Dialysis) and Project I.D. # J-11407-17 (add one dialysis station to Johnston Dialysis Center).

### **Need Determination**

The applicant is proposing to relocate four dialysis stations from Zebulon Kidney Center in Wake County to Johnston County, therefore there are no need methodologies in the 2018 State Medical Facilities Plan (2018 SMFP) applicable to this review.

### **Policies**

There is one policy in the 2018 SMFP which is applicable to this review. *Policy ESRD-2: Relocation of Dialysis Stations*, on page 27. Policy ESRD-2 states:

*“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties. Certificate of need applicants proposing to relocate dialysis stations to a contiguous county shall:*

- 1. Demonstrate that the facility losing dialysis stations or moving to a contiguous county is currently serving residents of that contiguous county; and*
- 2. Demonstrate that the proposal shall not result in a deficit, or increase an existing deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*
- 3. Demonstrate that the proposal shall not result in a surplus, or increase an existing surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.”*

The applicant proposes the relocation of four dialysis stations from Zebulon Kidney Center in Wake County to Johnston Dialysis Center in Johnston County. According to Table D in the July 2018 SDR, there is a deficit of nine dialysis stations in Johnston County and a surplus of eleven dialysis stations in Wake County. Thus, the proposed relocation of four stations from Wake County to Johnston County would reduce the surplus of stations in Wake County to seven dialysis stations as well as reduce the deficit of stations in Johnston County to five dialysis stations.

In Section B.3, page 8, the applicant states,

*“Relocation of four stations from Wake County to Johnston County will not create a deficit of stations in Wake County.*

*Relocation of four stations to Johnston County from Wake County will not create a surplus of stations in Johnston County.”*

Additionally, Wake County is a contiguous county to Johnston County. The applicant adequately demonstrates that the proposed relocation of four dialysis stations from Zebulon Kidney Center in Wake County to Johnston Dialysis Center in Johnston County is consistent with Policy ESRD-2.

### **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

The applicant proposes to relocate four dialysis stations from Zebulon Kidney Center to Johnston Dialysis Center for a total of 32 dialysis stations at Johnston Dialysis Center upon completion of this project, Project I.D. # J-11372-17 (develop a new 10-station dialysis facility by relocating two dialysis stations from FMC Four Oaks, four stations from Johnston Dialysis Center and four stations from FMC Hope Dialysis) and Project I.D. # J-11407-17 (add one dialysis station to Johnston Dialysis Center).

### **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 18, respectively, the applicant provides the projected and historical patient origin for Johnston Dialysis Center in-center patients, as illustrated in the table below.

County of Residence	Current as of 6/30/2018		OY1 FY2020	OY2 FY2021	County Patients as a Percent Of Total	
	In-Center Patients	% of Total	In-Center Patients	In-Center Patients	OY1 FY2020	OY2 FY2021
Johnson	101.0	99.1%	103.0	113.3	98.1%	98.2%
Nash	0.0	0.0%	1.0	1.0	1.0%	0.9%
Wayne	1.0	0.9%	1.0	1.0	1.0%	0.9%
<b>TOTAL</b>	<b>102.0</b>	<b>100.0%</b>	<b>104.0</b>	<b>114.0</b>	<b>100.0%</b>	<b>100.0%</b>

In Section C.1, 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.

On pages 13-15, the applicant states:

- The applicant begins the projections for Johnston Dialysis Center by using the ending in-center patient census of 101 patients from Johnston County, as of June 30, 2018.
- The applicant uses a 10% annual growth rate to project the Johnston County patient population forward. The applicant states it does not believe that the Johnston County Five Year Average Annual Change Rate (AACR) of 6.6% is appropriate because of the historical growth at the facility. The applicant further states the facility has increased by 10 patients since December 31, 2017 and experienced an average annual growth of 11.2% from June 30, 2014 - June 30, 2018.
- The applicant does not project an increase in the patient population from Wayne County.
- The applicant projects, based on a letter of support, that one patient currently dialyzing at Zebulon Kidney Center, but residing in Nash County, will transfer to Johnston Dialysis Center.
- The applicant includes seven letters of support from patients residing in Johnston County and dialyzing at Zebulon Kidney Center who have expressed an interest in transferring their care to Johnston Dialysis Center.

- The applicant subtracts the 21 patients projected to transfer their care to the new FKC Selma facility effective June 30, 2019. Those 21 patients were originally expected to transfer their care effective December 31, 2018, however, the applicant reports the FKC Selma project is delayed by six months. (see Project I.D. # J-11372-17).
- The applicant projects that two patients currently dialyzing at Johnston Dialysis Center will transfer their care to FKC West Johnston effective December 31, 2019.
- Operating Year 1 (OY1) = July 1, 2019 through June 30, 2020, Fiscal Year (FY) 2020.  
Operating Year 2 (OY2) = July 1, 2020 through June 30, 2021, FY 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 Johnston County patient census of Johnston Dialysis Center on June 30, 2018.
- the applicant grows the Johnston County patient population by 10% annually, which the applicant states is more reflective of the facility's historical growth, instead of the July 2018 SDR five-year AACR for Johnston County of 6.6%.
- the applicant holds utilization constant for its patients from Wayne County and adds one patient from Nash County, and
- the utilization rate of the in-center patients projected to be dialyzing at Johnston Dialysis Center by the end of the first year is above the minimum standard of 3.2 patients per station per week.

#### Projected Utilization

In Section C, page 15, the applicant provided the methodology used to project in-center utilization, as illustrated in the following table,

Johnston Dialysis Center  
J-11540-18  
Page 6

Begin with Johnston County patients dialyzing at Johnston Dialysis Center as of June 30, 2018.	101
Project the Johnston County patient population forward one year to June 30, 2019 using an annual growth rate of 10%.	$101 \times 1.10 = 111.1$
Subtract 21 Johnston County patients projected to transfer their care to FKC Selma.	$111.1 - 21 = 90.1$
Add 7 patients currently dialyzing at Zebulon Kidney Center who have expressed an interest in transferring their care to Johnston Dialysis Center.	$90.1 + 7 = 97.1$
Add 1 patient from Wayne County and 1 patient from Nash County. This is the projected starting census for Johnston Dialysis Center, as of June 30, 2019.	$97.1 + 2 = 99.1$
Project the Johnston County patient population forward six months to December 31, 2019 using one half of the projected yearly growth rate of 10% ( $10/2=5\%$ ).	$99.1 \times 1.05 = 104.155$
Subtract 2 patients projected to transfer their care to FKC West Johnston.	$104.155 - 2 = 102.155$
Project the Johnston County patient population forward six months to June 30, 2020 using one half of the projected yearly growth rate of 10% ( $10/2=5\%$ ).	$102.155 \times 1.05 = 107.26275$
<b>OY1:</b> Add in one patient from Wayne County and one patient from Nash County. This is the projected ending census for OY 1.	$107.26275 + 2 = 109.26275$
Project the Johnston County population forward one year to June 30, 2021 using an annual growth rate of 10%.	$109.26275 \times 1.10 = 120.189025$
<b>OY2:</b> Add in one patient from Wayne County and one patient from Nash County. This is the projected ending census for OY 2.	$120.189025 + 2 = 122.189025$

The applicant provides the assumptions for the projected in-center utilization on pages 13-15, as summarized below:

- Beginning census of Johnston County patients, June 30, 2018, is as listed in the ESRD Data Collection Forms submitted to DHSR Healthcare Planning in August 2018.
- OY1 is the period from July 1, 2019 through June 30, 2020.
- OY2 is the period from July 1, 2020 through June 30, 2021.
- The applicant includes letters of support in Exhibit C.1 of patients currently dialyzing at Zebulon Kidney Center who have expressed a willingness to consider transferring their dialysis care to Johnston Dialysis Center.
- The applicant projects the Johnston County patient census growth rate forward using 10% which is higher than the Johnston County Five Year AACR of 6.6%, as reported in the July 2018 SDR. The applicant states that the growth rate used is based on the historical growth at Johnston Dialysis Center.
- The Wayne County census will be held constant.

In Section C.2, pages 15-16, the applicant states:

*“In this application, BMA has projected a patient population of 104 in-center patients, to be dialyzing at the BMA Johnston facility at the end of the first year. Failure to add these stations to the BMA Johnston facility will lead to higher utilization rates at the facility. Utilization by 104 patients on 32 dialysis stations is calculated to be 3.25 patients per station, or 81.25% utilization.”*

On page 15, the applicant projects to serve 104 in-center patients in OY1 and 114 in-center patients in OY2. Thus, the applicant projects that Johnston Dialysis Center will have a utilization rate of 81.25% or 3.25 patients per station per week ( $104 \text{ patients} / 32 \text{ stations} = 3.25 / 4 = 0.8125$  or 81.25%) in OY1. The projected utilization of 3.25 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 Johnston County patients of Johnston Dialysis Center,
- the applicant grows the Johnston County patient census by 10% which is higher than the than the Johnston County Five Year AACR of 6.6%, as reported in the July 2018 SDR. The applicant states that the growth rate used is based on the historical growth at Johnston Dialysis Center, and
- the resulting utilization rate at Johnston Dialysis Center 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

In Section C, page 13, the applicant states Johnston Dialysis Center does not offer home dialysis therapies. Those patients that require home hemodialysis or peritoneal dialysis are referred to FMC Stallings Station. In Exhibit I.1, the applicant provides a copy of the home training agreement.

#### Access

In Section L.1(a), pages 48-49, the applicant states that each of BMA’s 112 facilities in 47 North Carolina counties has a patient population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, or other traditionally underserved persons. Services are provided to all patients, regardless of their ability to pay. In Section L.1, page 49, the applicant provides the projected payor mix during the second full fiscal year of operation following completion of the project (FY2020) for Johnston Dialysis Center, as illustrated below.

Payor Source	Percent of In-Center Patients
Self Pay/ Indigent/ Charity	2.45%
Medicare	59.54%
Medicaid	16.90%
Commercial Insurance	7.79%
Medicare / Commercial	11.90%
Misc. (VA)	1.41%
<b>Total</b>	<b>100.00%</b>

As illustrated in the table above, in FY2021 the applicant projects that 88.34% of all Johnston Dialysis Center patients were Medicare or Medicaid recipients. On page 49, the applicant states its projected payor mix in project year (PY) 2 is based on the facility's "most recent rolling 12 months of historical performance at the facility".

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.



The applicant proposes to relocate four dialysis stations from Zebulon Kidney Center to Johnston Dialysis Center for a total of 32 dialysis stations at Johnston Dialysis Center upon completion of this project, Project I.D. # J-11372-17 (develop a new 10-station dialysis facility by relocating two dialysis stations from FMC Four Oaks, four stations from Johnston Dialysis Center and four stations from FMC Hope Dialysis) and Project I.D. # J-11407-17 (add one dialysis station to Johnston Dialysis Center). Upon completion of this project and Project I.D. # J-11402-17, Zebulon Kidney Center will be certified for 26 stations (28 - 4 + 2 + 26).

In Section D, pages 20-21, the applicant explains why it believes the needs the applicant explains why it believes the needs of the population presently utilizing the services to be reduced, eliminated or relocated will be adequately met following completion of the project.

The applicant assumes that the number of in-center patients at Zebulon Kidney Center who live in Wake County will increase at 4.3% per year based on the Five Year AACR for Wake County, as reported in Table D of the July 2018 SDR. The applicant does not assume growth of the 45 patients residing outside of Wake County currently dialyzing at Zebulon Kidney Center. In Section D.1, page 20, the applicant calculates the in-center patient census for Zebulon Kidney Center starting June 30, 2018 through June 30, 2019, summarized as follows:

<b>Zebulon Kidney Center</b>	
BMA begins with the Wake County patient census as of June 30, 2018.	48
BMA projects this census forward one year using the Wake County Five Year Average Annual Change Rate of 4.3% to June 30, 2019.	$48 \times 1.043 = 50.1$
BMA adds the 45 patients from other counties*	$50.1 + 45 = 95.1$
Subtract 7 Johnston County patients and 1 Nash County patient projected to transfer their care to Johnston Dialysis Center.	$95.1 - 8 = 87.1$
Projected census as of June 30, 2019	87.1

\*Other counties include: Franklin, Johnston, Nash, and Wilson

In Section D, page 21, the applicant states that BMA rounds the patient population of 87.1 up to 88 in-center patients for a utilization of 84.62% or 3.38 patients per station, per week. This is based on 88 in-center patients dialyzing on 26 certified dialysis stations ( $88 / 26 = 3.3846$ ;  $3.3846 / 4 = 0.8462$  or 84.62%).

Projected utilization is reasonable and adequately supported based on the following reasons:

- the applicant begins its utilization projection with the existing Wake County patients of Zebulon Kidney Center,
- the applicant grows the Wake County patient census by the Wake County Five Year AACR of 4.3%, as reported in the July 2018 SDR, and

- the resulting utilization rate at Zebulon Kidney Center following completion of this project and Project I.D. # J-11402-17 is above the minimum standard of 3.2 patients per station per week.

On page 21, the applicant states, *“This relocation of stations will not have any effect upon the ability of low income persons, racial and ethnic minorities, women, handicapped persons, the elderly and other underserved groups to obtain needed health care.”*

The applicant states that the proposed relocation of stations and transfer of patients will not have an effect upon access to care for any patient.

### **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 applicant adequately demonstrates that:

- The needs of the population currently using the services to be reduced, eliminated or relocated will be adequately met following project completion.
- The project will not adversely impact the ability of underserved groups to access these services following project completion.

- (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 relocate four dialysis stations from Zebulon Kidney Center to Johnston Dialysis Center for a total of 32 dialysis stations at Johnston Dialysis Center upon completion of this project, Project I.D. # J-11372-17 (develop a new 10-station dialysis facility by relocating two dialysis stations from FMC Four Oaks, four stations from Johnston Dialysis Center and four stations from FMC Hope Dialysis) and Project I.D. # J-11407-17 (add one dialysis station to Johnston Dialysis Center).

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 Johnston Dialysis Center continues to grow. Failure to add additional stations could result in a lack of capacity and the ability to accept patient admissions. Therefore, this alternative was rejected.
- Relocate stations from another facility other than Zebulon Kidney Center - The applicant states there was no other facility outside of Johnston County that provided care for as many Johnston County patients. According to Table A of the July 2018 SDR, Zebulon Kidney Center provided in-center care to 20 residents of Johnston County, as of December 31, 2017. Therefore, this alternative was rejected.
- Relocate stations from FMC Four Oaks - the utilization at FMC Four Oaks, as reported in the July 2018 SDR, is 72.73%. BMA was approved in Project I.D. # J-11372-17 to relocate two stations to assist with the development of a new facility, FKC Selma. The applicant states that assuming the in-center census at FMC Four Oaks remains constant, this will be 64 patients dialyzing on 20 stations for a utilization rate of 80% or 3.2 patients per station per week. To relocate additional stations from this facility has the potential to jeopardize future admissions to FMC Four Oaks. Therefore, the applicant rejected this alternative.

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

- Johnston Dialysis Center is currently operating above 80% capacity, and
- to maintain the status quo does not address the need for additional stations at the facility and could result in a lack of capacity to accept new admissions.

### **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 Johnston Dialysis Center shall materially comply with all representations made in the certificate of need application.**

2. **Pursuant to Policy ESRD-2, Bio-Medical Applications of North Carolina, Inc. shall relocate 4 dialysis stations from Zebulon Kidney Center to Johnston Dialysis Center for a total of no more than 32 dialysis stations at Johnston Dialysis Center upon completion of this project, Project I.D. # J-11372-17 and Project I.D. # J-11407-17.**
  3. **Upon completion of this project, Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify four dialysis stations at Zebulon Kidney Care for a total of no more than 26 dialysis stations at Zebulon Kidney Care.**
  4. **Bio-Medical Applications of North Carolina, Inc. d/b/a Johnston Dialysis Center shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

## C

The applicant proposes to relocate four dialysis stations from Zebulon Kidney Center to Johnston Dialysis Center for a total of 32 dialysis stations at Johnston Dialysis Center upon completion of this project, Project I.D. # J-11372-17 (develop a new 10-station dialysis facility by relocating two dialysis stations from FMC Four Oaks, four stations from Johnston Dialysis Center and four stations from FMC Hope Dialysis) and Project I.D. # J-11407-17 (add one dialysis station to Johnston Dialysis Center).

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

In Section F.1, page 25, the applicant projects no capital cost for the proposed project. In Section F.10, page 28, the applicant projects no start-up expenses or initial operating expenses because Johnston Dialysis Center is an existing operational facility.

### **Financial Feasibility**

In Section R, the applicant provided pro forma financial statements for the first two full fiscal years of operation following completion 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 FY2019	Operating Year 2 FY2020
Total Treatments	14,968	16,153
Total Gross Revenues (Charges)	\$59,692,384	\$64,418,164
Total Net Revenue	\$4,104,612	\$4,429,570
Average Net Revenue per Treatment	\$274.23	\$274.23
Total Operating Expenses (Costs)	\$3,446,776	\$3,801,721
Average Operating Expense per Treatment	\$230.28	\$235.36
Net Income	\$657,836	\$627,849

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

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 relocate four dialysis stations from Zebulon Kidney Center to Johnston Dialysis Center for a total of 32 dialysis stations at Johnston Dialysis Center upon completion of this project, Project I.D. # J-11372-17 (develop a new 10-station dialysis facility by relocating two dialysis stations from FMC Four Oaks, four stations from Johnston Dialysis Center and four stations from FMC Hope Dialysis) and Project I.D. # J-11407-17 (add one dialysis station to Johnston Dialysis Center).

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 July 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.

<b>JOHNSTON COUNTY DIALYSIS FACILITIES            EXISTING &amp; APPROVED CERTIFIED STATIONS &amp;            UTILIZATION as of December 31, 2017</b>				
<b>Dialysis Facility</b>	<b>Certified Stations 12/31/17</b>	<b># In-center Patients</b>	<b>Percent Utilization</b>	<b>Patients per Station</b>
FMC Four Oaks	22	64	72.73%	2.9091
FMC Stallings Station	24	85	88.54%	3.5417
FKC Selma*				
FKC West Johnston*				
Johnston Dialysis Center	25	92	92.00%	3.6800

Source: July 2018 SDR

\*Approved, but not operational.

As shown in the table above, Johnston Dialysis Center operated with a utilization rate of 92.00%. In Section G, page 33, the applicant states, *“the July SDR reports an [sic] nine station deficit for Johnston County. BMA is addressing some of that deficit by filing to relocate four stations from Wake County, into Johnston County, with this application.”*

In Section G, pages 33-34, 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, *“These facilities are dispersed across Johnston County ... BMA believes the relocation of these four station [sic] to BMA Johnston is necessary, cost effective and will not unnecessarily duplicate existing health services.”*

The applicant proposes the relocation of four dialysis stations from Zebulon Kidney Center in Wake County to Johnston Dialysis Center in Johnston County. According to Table D in the July 2018 SDR, there is a deficit of nine dialysis stations in Johnston County and a surplus of eleven dialysis stations in Wake County. Thus, the proposed relocation of four stations from Wake County to Johnston County would reduce the surplus of stations in Wake County to seven dialysis stations as well as reduce the deficit of stations in Johnston County to five dialysis stations.

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

- The proposal decreases the surplus of dialysis stations in Wake County and decreases the deficit of dialysis stations in Johnston County.
- The applicant adequately demonstrates that the proposed addition of four dialysis stations at Johnston Dialysis Center 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 35, the applicant provides current and projected staffing for the proposed services, as illustrated in the following table.

POSITION	CURRENT # FTES CY2017	PROJECTED # FTES 2 <sup>ND</sup> FULL FISCAL YEAR (FY2021)
Registered Nurse	4.00	5.00
LPN	1.00	1.00
Patient Care Technician	10.00	12.00
Clinical Manager	1.00	1.00
Admin. (Dir. Ops)	0.20	0.20
Dietician	1.00	1.00
Social Worker	1.00	1.00
In-Service	0.50	0.50
Clerical	1.00	1.00
Chief Tech	0.50	0.50
Equipment Tech	1.00	1.00
<b>Total</b>	<b>21.20</b>	<b>24.20</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 74-75, which is found in Section R. In Section H, pages 35-36, 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 his interest in continuing to serve as the medical director of Johnston Dialysis Center. In Exhibits H.1 and H.2, the applicant provides supporting documentation.

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

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.



In Section I, page 38, the applicant provides a list of the necessary ancillary and support services, as illustrated below.

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

The applicant provides supporting documentation in Exhibits I.2-5. Exhibits I-2 through I-4, respectively, contain copies of an agreement for home training with FMC Stallings Station, Spectra for laboratory services, Johnston Memorial Hospital for transfer agreement and University of North Carolina for transplant services.

In Section I, pages 39-41, the applicant describes its existing and proposed relationships with other local healthcare and social service providers and provides supporting documentation in Exhibit 5.

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

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 52, the applicant provides the historical payor mix from January 1, 2017 to December 31, 2017 for the proposed services, as shown in the table below.

<b>Payor Source</b>	<b>Percent of Total Patients</b>
Self Pay/ Indigent/ Charity	1.04%
Medicare	60.98%
Medicaid	17.33%
Commercial Insurance	7.14%
Medicare / Commercial	11.60%
Misc. (VA)	1.91%
<b>Total</b>	<b>100.00%</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**
2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate
Johnston	13%	51%	31%	13%	10%	14%
Statewide	16%	51%	37%	15%	10%	12%

Source: <http://www.census.gov/quickfacts/table/US/PST045217> Latest Data 7/1/17 as of 7/17/18

\* Excludes "White alone, not Hispanic or Latino"

\*\* "Estimates are not comparable to other geographic levels due to methodology differences that may exist between different data sources. 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., V2017) refers to the final year of the series (2010 thru 2017). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consisting of North Carolina, South Carolina and Georgia, provides an Annual Report which includes aggregate ESRD patient data from all three states. The 2016 Annual Report does not provide state-specific ESRD patient data, but the aggregate data is likely to be similar to North Carolina’s based on the Network’s recent annual reports which included state-specific data.

The IPRO SA Network 6 2016 Annual Report (pages 25-26<sup>1</sup>) provides the following prevalence data on dialysis patients by age, race, and gender. As of December 31, 2016, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 66% were other than Caucasian and 45% were female.

**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

<sup>1</sup> <https://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/07/NW6-2016-Annual-Report-FINAL.pdf>

population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 51, 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 51, 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

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 49, 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**

<b>Payor Source</b>	<b>Percent of Total Patients</b>
Self Pay/ Indigent/ Charity	2.45%
Medicare	59.54%
Medicaid	16.90%
Commercial Insurance	7.79%
Medicare / Commercial	11.90%
Misc. (VA)	1.41%
<b>Total</b>	<b>100.00%</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 71.44% Medicare patients (includes Medicare and Medicare/Commercial) and 16.90% Medicaid patients.

On page 49, 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 Johnston Dialysis Center.

**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.

- (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 51, 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

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.1.

### **Conclusion**

The Agency reviewed the:

- Application
- 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

The applicant proposes to relocate four dialysis stations from Zebulon Kidney Center to Johnston Dialysis Center for a total of 32 dialysis stations at Johnston Dialysis Center upon completion of this project, Project I.D. # J-11372-17 (develop a new 10-station dialysis facility by relocating two dialysis stations from FMC Four Oaks, four stations from Johnston Dialysis Center and four stations from FMC Hope Dialysis) and Project I.D. # J-11407-17 (add one dialysis station to Johnston Dialysis Center).

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 July 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.

<b>JOHNSTON COUNTY DIALYSIS FACILITIES            EXISTING &amp; APPROVED CERTIFIED STATIONS &amp;            UTILIZATION as of December 31, 2017</b>				
<b>Dialysis Facility</b>	<b>Certified Stations 12/31/17</b>	<b># In-center Patients</b>	<b>Percent Utilization</b>	<b>Patients per Station</b>
FMC Four Oaks	22	64	72.73%	2.9091
FMC Stallings Station	24	85	88.54%	3.5417
FKC Selma*				
FKC West Johnston*				
Johnston Dialysis Center	25	92	92.00%	3.6800

Source: July 2018 SDR

\*Approved, but not operational.

BMA is the only provider of dialysis services in Johnston County. In Section N.1, page 54, 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 54, the applicant states:



*“BMA does not expect this proposal to have effect on the competitive climate in Johnston County. BMA does not project to serve dialysis patients currently being served by another provider. The projected patient population for the BMA Johnston facility begins with patients currently served by BMA at other BMA locations within the county, and a growth of that patient population at a rate consistent with the recent facility history.”*

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 5, the applicant states that BMA is a wholly owned subsidiary of Fresenius Medical Care Holdings (FMCH), Inc. In Exhibit A.4, the applicant provides a list of its North Carolina dialysis facilities.

In Section O, page 59, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in none of these facilities. The applicant states in Section D.3, page 59 that all facilities are currently in compliance with all Medicare conditions of participation. After reviewing and considering information provided by the applicant and considering the quality of care provided at all 112

facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective 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- Johnston Dialysis Center 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 13-15, the applicant demonstrates that Johnston Dialysis Center will serve a total of 104 in-center patients at the end of OY1 for a utilization rate of 81.25% or 3.5 patients per station per week (104 patients / 32 stations = 3.25 / 4 = 0.8125 or 81.25%). 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 -15, 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.