

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: April 5, 2018

Findings Date: April 5, 2018

Project Analyst: Bernetta Thorne-Williams

Team Leader: Lisa Pittman

Project ID #: J-11435-17

Facility: Fresenius Kidney Care West Johnston

FID #: 170323

County: Johnston

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

Project: Develop a new 10-station dialysis facility by relocating ten dialysis stations from FMC Stallings Station for a total of 14 stations remaining at FMC Stallings Station upon project completion

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

The applicant, Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a Fresenius Kidney Care West Johnston (FKC West Johnston) proposes to relocate ten dialysis stations from FMC Stallings Station to develop the proposed new 10-station dialysis facility in Garner (Johnston County). The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations. Upon project completion FMC Stallings Station will be certified for 14 dialysis stations.

Need Determination

The applicant is proposing to relocate existing dialysis stations within Johnson County, therefore there are no need methodologies in the 2017 State Medical Facilities Plan (2017 SMFP) applicable to this review.

Policies

Policy ESRD-2 is applicable to this review. Policy ESRD-2 of the 2017 SMFP 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 contiguous counties 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 to develop a new 10-station dialysis facility, to be named FKC West Johnston, in Garner, Johnston County by relocating ten dialysis stations from FMC Stallings Station, also in Johnston County. Therefore, the applicant demonstrates conformity 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 develop a new 10-station dialysis facility in Garner by relocating ten dialysis stations from FMC Stallings Station to the proposed FKC West Johnston Dialysis.

Patient Origin

On page 373, the 2017 SMFP defines the service area for dialysis stations as “*the 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.

FKC West Johnson will be a new facility in Johnston County and therefore has no existing patient origin.

In Section C.1, page 15, the applicant identifies the patient population it proposes to serve for the first two years of operation following project completion, as illustrated in the following table:

**FKC West Johnston
 Projected Patient Origin by County**

County	Operating Year 1 1/1/19 –12/31/19	Operating Year 2 1/1/20-12/31/20	County Patients as Percent of Total	
	In-Center Patients	In-Center Patients	Year 1	Year 2
Johnston	34.0	36.2	100.0%	100.0%
Total*	34	36	100.0%	100.0%

*Rounded down to the whole patient

The applicant does not propose to serve home hemodialysis or peritoneal dialysis patients. On page 15, the applicant states that patients who might be candidates for home dialysis will be referred to FMC Stallings Station.

The applicant provides the assumptions and methodology used to project patient origin on pages 15-16. The applicant adequately identifies the population to be served.

Analysis of Need

In Section C, pages 15-17, the applicant states the need for the proposed new FKC West Johnston Dialysis facility is based on the following factors:

- A significant number of current BMA patients reside in the area of the proposed facility near the intersection of NC Highway 42 and Interstate 40 in Johnston County. (page 15).
- Letters of support from 34 in-center patients who reside in close proximity to the proposed facility. (page 15 and Exhibit C.1)

The applicant provides a table on page 16, which depicts the patients by residence ZIP Code and the facility where they are currently receiving dialysis services, as illustrated below.

BMA Facility	FKC West Johnston								Totals
	ZIP Code of Residence								
	27501	27504	27520	27529	27577	27592	27603	27529 (Wake)	
Four Oaks		3							3
Fuquay	1		1			4			6
Johnston			2						2
New Hope						1			1
SW Wake			3						3
Stallings Station			12	3	2		1	1	19
Totals	1	3	18	3	2	5	1	1	34

- The applicant assumes that 32 of the 34 patients who provided letters of support will transfer their care to the proposed FKC West Johnston facility based upon a reduction in travel distance. (page 16)
- The applicant assumes the Johnston County dialysis patients transferring to the proposed facility will grow at a rate commensurate with the Johnston County Five Year Average Annual Change Rate as published in the July 2017 SDR of 6.3%. (page 21)

Projected In-center Utilization

The applicant projects that Operating Year One (OY1) and Operating Year Two (OY2) for the proposed project will be Calendar Year (CY) 2020 and CY2021, respectively. In Section C.1, page 16, the applicant provides its methodology for projecting in-center (IC) utilization as follows:

FKC West Johnston IN-CENTER	
In-center Methodology:	
BMA begins 32 Johnston County IC dialysis patients upon project certification December 31, 2019.	32
BMA projects this census forward one year using the Johnston County Five Year Average Annual Change Rate of 6.3% to December 31, 2020. This is the end of OY1.	$32 \times 1.063 = 34.02$
BMA projects this Johnston County patient population forward to December 31, 2021. This is the ending census for Operating Year 2.	$34.02 \times 1.063 = 36.16$

The applicant rounds down to the nearest whole number. Therefore, the applicant projects to serve 34 in-center patients or 3.4 patients per station per week ($34/10 = 3.4$) by the end of OY1 with a utilization rate of 85% ($3.4/4 = 0.85$ or 85%) and 36 in-center patients or 3.6 patients per station per week ($36/10 = 3.6$) with a utilization rate of 90% ($3.6/4 = 0.9$ or 90%) by the end of OY2 for the proposed facility. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

Projected utilization is based on reasonable and adequately supported assumptions regarding patient support and continued growth. In summary, the applicant adequately identifies the population to be served and adequately demonstrates the need that population has for the proposed facility.

Access

In Section C, page 18, the applicant states,

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

In Section L.1(a), pages 58-59, 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. In Section L, page 59, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

FKC West Johnston	
PROJECTED PAYOR SOURCE (OY2) (CY2021)	PERCENT OF TOTAL IN-CENTER PATIENTS
Self Pay/Indigent/Charity	0.95%
Medicare	68.64%
Medicaid	4.37%
Commercial Insurance	9.21%
Medicare/Commercial	14.39%
Miscellaneous (Includes VA)	2.43%
Total	100.00%

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.

C

The applicant proposes to develop a new 10-station dialysis facility, to be named FKC West Johnston, in Garner, Johnston County by relocating ten existing dialysis stations from FMC Stallings Station in Clayton, Johnston County. Upon completion of this project, FMC Stallings Station will be certified for 14 dialysis stations (24 - 10 = 14).

The following table shows the proposed relocation of stations and transfer of Johnston County dialysis patients projected in the proposed project.

FMC Stallings Station	Number of Stations	Number of Patients
Current as of 6/30/17	24	83
Relocating to West Johnston	10	14
Remaining at FMC Stallings Station	14	64

The applicant assumes that the number of in-center patients at FMC Stallings Station who live in Johnston County will increase at 6.3% per year based on the Five Year AACR for Johnston County, as reported in Table D of the July 2017 SDR. The applicant does not assume growth in the three patients from Wake County currently dialyzing at FMC Stallings Station who will stay at Stallings Station. In Section D.1, page 25, the applicant calculates the in-center patient census for FMC Stallings Station starting June 30, 2017 through December 31, 2019, summarized as follows:

FMC Stallings Station	
BMA begins with the Johnston County patient census as of June 30, 2017.	77
BMA projects this census forward for six months using the Johnston County Five Year Average Change Rate to December 31, 2017.	$[77 \times (.063 / 12 \times 6)] + 77 = 79.4$
BMA projects this census forward for one year to December 31, 2018.	$79.04 \times 1.063 = 84.4$
BMA projects this census forward for one year to December 31, 2019.	$84.4 \times 1.063 = 89.7$
Subtract 11 Johnston County residents projected to transfer their care to FKC West Johnston.	$89.7 - 11 = 78.7$
Add three of the six Wake County patients projected to remain at FMC Stallings Station.	$78.7 + 3 = 81.7$

On page 25, the applicant states that BMA rounds the patient population of 81.7 up to 82 in-center patients for a utilization of 146.4% or 5.86 patients per station, per week. This is based on 82 in-center patients dialyzing on 14 certified dialysis stations ($82 / 14 = 5.8571$; $5.8571 / 4 = 1.4642$ or 146.4%). On page 25, the applicant states, “BMA readily acknowledges that utilization rates in excess of four patient [sic] per station necessarily result in a third, or evening dialysis shift. FMC Stallings Station does not currently operate a third, or evening dialysis shift, but will do so when the patient census requires.” In addition the facility will qualify for additional stations per the facility need methodology, if the census remains high.

In Section L.1(b), page 59, the applicant states that the projected payor mix at the proposed new facility is based on the historical payor mix of FMC Stallings Station. Thus, the applicant states that the proposed relocation of stations and transfer of patients will not have an adverse impact 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

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

In Section E, page 29, the applicant describes the alternatives considered and explains why each alternative is either more costly or less effective than the alternative proposed in the 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 of the number of people currently dialyzing at a BMA facility in Johnston and Wake counties who live in closer proximity to the proposed FKC West Johnston facility. Therefore, this alternative was rejected.
- Continue with the expansion of FMC Stallings Station - On June 8, 2017, in Project J-11310-17, BMA was approved to relocate four dialysis stations from FMC Four Oaks to FMC Stallings Station for a total of 28 dialysis stations at FMC Stallings Station upon project completion. On November 15, 2017, BMA surrendered the CON for this project. BMA concluded that the expansion was costly and provided limited opportunity for future expansion. Therefore, this alternative was rejected.
- Develop a facility in another area of Johnston County - After an evaluation of the current patient population served at BMA and Fresenius related facilities in Johnston County and an analysis of projected population growth, the applicant concluded that the proposed area in western Johnston County would be best served by a new facility. Therefore, development of a facility in another area of Johnston County was not considered to be an effective alternative.
- Development of a larger facility - After evaluation of the current patient population and the projected population growth, the applicant concluded that a larger facility was not needed and therefore would not be an effective alternative.
- Inclusion of home hemodialysis and peritoneal dialysis services - The applicant concluded that the current home patient population is well served by the FMC Stallings

Station facility. The applicant will save money by not adding home hemodialysis services to the proposed facility. Therefore, this alternative was rejected.

Thus, after considering the above alternatives, the applicant states on page 29 that its proposal to develop a new 10-station facility in Garner in the western part of Johnston County by relocating ten existing stations from FMC Stallings Station is the most efficient or cost effective alternative. The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need because, *“Given the residence location of patients served by BMA and projected to be served at the FKC West Johnston facility, the applicant has made the most effective choice.”* (See page 29)

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 Fresenius Kidney Care West Johnston 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 develop a new kidney disease treatment center to be known as Fresenius Kidney Care West Johnston by relocating ten dialysis stations from FMC Stallings Station.**
- 3. Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Kidney Care West Johnston shall install plumbing and electrical wiring through the walls for no more than 10 dialysis stations, which shall include any isolation or home hemodialysis stations.**
- 4. Upon completion of this project, Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify ten dialysis stations from FMC Stallings Station for a total of no more than fourteen dialysis stations at FMC Stallings Station.**
- 5. Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Kidney Care West Johnston 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 develop a new 10-station dialysis facility, to be named FKC West Johnston, in Garner, Johnston County by relocating ten existing dialysis stations from FMC Stallings Station in Clayton, Johnston County.

Capital and Working Capital Costs

In Section F.1, page 32, the applicant projects \$1,875,991 in capital costs to develop the proposed project as summarized below:

Projected Capital Costs	
	Total Capital Costs
Construction Costs	\$1,263,429
Sub-Total Miscellaneous Costs	\$612,563
Total Capital Cost	\$1,875,991

In Sections F.10 - F.12, pages 35-36, the applicant estimates start-up expenses of \$122,469 and initial operating expenses of \$1,016,680, for a total working capital of \$1,139,149.

In Section F.1, page 31, the applicant provides the assumptions used to project the capital cost.

Availability of Funds

In Section F.2, page 33, the applicant states it will finance the capital costs with accumulated reserves/owner's equity of Fresenius Medical Care Holdings, Inc. (FMC). In Section F.13, page 37, the applicant states the working costs will be financed by the accumulated reserves of FMC.

Exhibit F.1 contains a letter dated November 15, 2017, from the Senior Vice President and Treasurer for FMCH, the parent company of BMA, which authorizes and commits cash reserves for the capital costs of the proposed project in the amount of \$1,875,991. Additionally the letter states,

“Further, I am authorized and do hereby authorize and commit cash reserves for the capital cost of \$1,875,991 as may be needed for this project. I am also authorized, and authorize an additional funds as may be necessary for the start-up costs in the new location.”

The letter contained in Exhibit F-1, does not specifically list the total working capital of the project as \$1,139,149, however, it is clear from the intent of the letter that the working capital needs of the project will be financed by FMC.

Exhibit F-2 contains the Subsidiaries Consolidated Financial Statements for FMC which indicates that it had \$357.9 million in cash and cash equivalents as of December 31, 2016, \$20.1 billion in total assets and \$10.5 billion in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of funds for the capital, working capital, and operating needs of the project.

Financial Feasibility

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

	Operating Year 1 CY2020	Operating Year 2 CY2021
Total Treatments	4,742	5,038
Total Gross Revenues (Charges)	\$18,911,096	\$20,091,544
Total Net Revenue	\$1,597,828	\$1,697,565
Total Operating Expenses (Costs)	\$1,525,020	\$1,575,332
Net Income	\$72,808	\$122,233

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 that the capital and working capital costs are based on reasonable and adequately supported assumptions.
 - The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal.
 - 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 develop a new 10-station dialysis facility in Garner to be named FKC West Johnston by relocating 10 dialysis stations from FMC Stallings Station.

On page 373, the 2017 SMFP defines the service area for dialysis stations as “*the 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 2017 SDR, there are currently three dialysis facilities in Johnston County, as illustrated below.

JOHNSTON COUNTY DIALYSIS FACILITIES EXISTING & APPROVED CERTIFIED STATIONS & UTILIZATION as of DECEMBER 31, 2016				
Dialysis Facility/Owner	Certified Stations 12/31/16	# In-center Patients	Percent Utilization	Patients per Station
FMC Four Oaks	22	58	65.91%	2.6364
FMC Stallings Station	24	78	81.25%	3.2500
Johnston Dialysis Center (FMC)	25	94	94.00%	3.7600
Totals	71	230	80.98%	3.2394

Source: July 2017 SDR.

In Section G, page 41, 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, “*BMA is currently serving a patient population residing in western Johnston County, near the proposed location for FKC West Johnston. The patients of this area are already dialyzing with BMA at another BMA facility.*” (See page 41)

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

- The proposal would not result in an increase in the number of dialysis stations in Johnston County.
- The applicant adequately provides documentation from patients willing to transfer their care to the proposed facility because the facility’s location is closer to their homes or more convenient to access.

Conclusion

The Agency reviewed the:

- Application
- Exhibits in the application

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.1, page 42, the applicant provides the projected staffing for FKC West Johnston in OY2 by full-time equivalent (FTE) staff, as shown below:

FKC West Johnston Proposed FTE Positions OY2	
Position	Total
Registered Nurse	1.50
Patient Care Technician	4.00
Clinical Manager	1.00
Administrator	0.15
Dietitian	0.40
Social Worker	0.40
Chief Tech	0.15
Equipment Tech	0.60
In-Service	0.15
Clerical	0.75
Total FTEs	9.10

Note: The Medical Director is a contracted position.

In Section H.3, page 43, the applicant describes its experience and process for recruiting and retaining staff. In Section H.7, page 45, the applicant provides the projected direct care staff for FKC West Johnston Dialysis in OY2 (CY2021). In Section H.6, page 44, the applicant states that dialysis services will be available Monday through Saturday from 6:00am – 4:00pm.

In Section I.3, page 47, the applicant identifies the medical director for the proposed facility as William Fan, M.D. Exhibit I.5 contains a copy of a letter from Dr. Fan expressing support for the proposed project and a willingness to serve as the Medical Director. Exhibit I.6 contains a copy of Dr. Fan's curriculum vitae.

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.1, page 46, the applicant includes a list of providers of the necessary ancillary and support services for the proposed project, explains how each will be made available and provides supporting documentation in Exhibit I. Exhibits I.1-4 contain documentation for home dialysis training, laboratory, hospital and transplant services, respectively. Exhibit I-5 contains a letter from the proposed medical director of the facility describing Nephrology services that will be offered by North Carolina Nephrology, P.A. The applicant discusses the project's coordination with the existing health care system in Sections I.3 and I.4, pages 47-49. 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 for the reasons stated above.

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

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the

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

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

NA

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

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

C

In Section K.2, page 53, the applicant states that the proposed facility will be developed in 2,203 square feet of leased space in a building located at 5771 NC Highway 42 in Garner. The applicant provides the proposed facility's line drawings in Exhibit K.1. The drawing depicts space with nine main floor dialysis stations and one isolation dialysis station, for a total of 10 dialysis stations. In Section F.1, page 31, the applicant states that it relies upon the Fresenius Facility Design and Maintenance Department to develop anticipated project development costs. On page 32, the applicant provides the proposed costs, including \$1,263,429 for construction upfit, \$612,562 in miscellaneous costs, including water treatment equipment, furniture, architect/engineering fees, and contingency for a total project cost of \$1,875,991. In Section K.1, pages 51-52, the applicant describes its plans for energy-efficiency, including water conservation. Costs and charges are described by the applicant in Section F, page 32, and in Section R pro forma financial statements.

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.

(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

FKC West Johnson is not an existing facility, therefore, it has no historical payor mix. However, in Section L.7, page 62, the applicant provides the historical payor mix for FMC Stallings Station for CY2016. This is the facility from which the applicant proposes to relocate the ten existing dialysis stations to develop the proposed new FKC West Johnston facility. Their payor mix is illustrated below:

FMC Stallings Station	
Payor Source	CY2016
Self Pay/Idigent/Charity	0.95%
Medicare	68.64%
Medicaid	4.37%
Commercial Insurance	9.21%
Medicare/Commercial	14.39%
Miscellaneous Including VA)	2.43%
Total	100.0%

Note: The applicant states on page 62 that totals may not sum due to rounding

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant's service area.

Percent of Population						
County	% 65+	% Female	% Racial 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 27-28¹. 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.

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. 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 handicapped persons, in Section L.3(e), pages 60-61, the applicant states the following:

¹http://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/05/2015_NW-6_Annual-Report_Final-11-29-2016.pdf

“Fresenius related facilities in North Carolina 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.6, page 61, the applicant states there have been no civil rights access complaints filed within the last five years against any BMA North Carolina facility.

The Agency reviewed the:

- Information in the application, including any exhibits.
- 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.1, page 59, the applicant projects that 87.4% of the patients who will receive in-center treatments at FKC West Johnston will have some or all of their services paid for by Medicare or Medicaid. The table below shows the projected OY2 (CY2021) payor sources for the facility for in-center patients.

FKC West Johnston	
PROJECTED PAYOR SOURCE (OY2) (CY2021)	PERCENT OF TOTAL IN-CENTER PATIENTS
Self Pay/Indigent/Charity	0.95%
Medicare	68.64%
Medicaid	4.37%
Commercial Insurance	9.21%
Medicare/Commercial	14.39%
Miscellaneous (Includes VA)	2.43%
Total	100.00%

In Section L1, page 59, the applicant states the projected payor mix is calculated based on the payor mix of FMC Stallings Station in Johnston County as of September 30, 2017. The projected payor mix is reasonable and adequately supported.

The applicant is conforming to this criterion based on a review of the:

- Information in the application, including any exhibits.
 - Information which was publicly available during the review and used by the Agency.
- (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 61, the applicant describes the range of means by which a person will have access to the dialysis services at the proposed FKC West Johnston facility, including referrals from nephrologists and hospital emergency departments.

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.

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

C

In Section M.1, page 63, the applicant states that health related education programs will be welcomed at the facility. Exhibit M.1 includes a letter from the applicant to the Director of Nursing Education Programs for Johnston Community College, dated November 14, 2017, inviting the school to include FKC West Johnston in its clinical rotations for its nursing students.

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 develop a new 10 station dialysis facility in Garner to be named FKC West Johnston Dialysis by relocating 10 dialysis stations from FMC Stallings Station.

On page 373, the 2017 SMFP defines the service area for dialysis stations as “*the 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 2017 SDR, there are currently three operational dialysis facilities in Johnston County, as illustrated below.

JOHNSTON COUNTY DIALYSIS FACILITIES EXISTING & APPROVED CERTIFIED STATIONS & UTILIZATION as of DECEMBER 31, 2016				
Dialysis Facility/Owner	Certified Stations 12/31/16	# In-center Patients	Percent Utilization	Patients per Station
FMC Four Oaks	22	58	65.91%	2.6364
FMC Stallings Station	24	78	81.25%	3.2500
Johnston Dialysis Center (FMC)	25	94	94.00%	3.7600
Totals	71	230	80.98%	3.2394

Source: July 2017 SDR.

In Section N.1, page 64, 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 cost-effectiveness, quality and access to the proposed services. On page 64, the applicant states,

“The applicant does not expect this proposal to have effect on the competitive climate in Johnston County. At this time, BMA is the only provider of dialysis services in the county. The applicant does not project to serve dialysis patients currently being served by another provider. The projected patient population for the FKC West Johnston facility begins with patients currently served by BMA at other nearby BMA locations, 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 July 2017 SDR.”

In addition, the applicant states that it must operate efficiently as a result of fixed Medicare and Medicaid reimbursement rates and projects that greater than 87% of the patients at FKC West Johnston will have their services covered by Medicare or Medicaid.

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 Bio-Medical Applications of North Carolina, Inc. is a wholly owned subsidiary of Fresenius Medical Care Holdings, Inc. On page 17, the applicant states, Fresenius operates 112 facilities in 48 North Carolina counties. In Section O, pages 68-69 and referenced Exhibits, the applicant identifies the one kidney disease treatment center located in North Carolina owned and operated by the applicant or an affiliated company that did not operate in compliance with the Medicare conditions of participation during the 18 month look-back period. BMA East Rocky Mount had an immediate jeopardy citation. The facility is back in compliance with the Medicare conditions of participation.

After reviewing and considering information provided by the applicant and by the 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 application is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. The specific criteria are discussed below:

10 NCAC 14C .2203 PERFORMANCE STANDARDS

- .2203(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*
- C- In Section C.1, pages 15-16 the applicant states the need for the proposed project. The applicant projects to serve 34 in-center patients or 3.4 patients per station per week ($34/10 = 3.4$) by the end of OY1 with a utilization rate of 85% ($3.4/4 = 0.85$ or 85%) and 36 in-center patients or 3.6 patients per station per week ($36/10 = 3.6$) with a utilization rate of 90% ($3.6/4 = 0.9$ or 90%) by the end of OY2 for the proposed facility. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b). The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.
- .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.*

-NA- The application is for the development of a new 10-station facility.

.2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*

-C- The applicant provides its assumptions, including the methodology by which patient utilization is projected in Section C-1, pages 15-16, the applicant provides the assumptions and methodology used to project utilization of the facility.