

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 8, 2017

Findings Date: June 8, 2017

Project Analyst: Bernetta Thorne-Williams

Team Leader: Lisa Pittman

Project ID #: J-11310-17

Facility: Fresenius Medical Care Stallings Station

FID #: 030941

County: Johnston

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

Project: Relocate four dialysis stations from FMC Four Oaks to FMC Stallings Station for a total of 28 stations upon completion of this project

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a Fresenius Medical Care Stallings Station (FMC Stallings Station) proposes to relocate four dialysis stations from FMC Four Oakes to FMC Stallings Station for a total of 28 certified dialysis stations at FMC Stallings Station and 18 certified dialysis stations at FMC Four Oaks upon project completion.

Need Determination

The 2017 State Medical Facilities Plan (2017 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2017 Semiannual Dialysis Report (SDR), the county need methodology shows there is no county need determination for Johnston County. Therefore, the applicant is not

eligible to apply for additional stations in its existing facility based on the county need methodology. The applicant is also not eligible to apply for additional stations in its existing facility based on the facility need methodology. The applicant does not propose to add new dialysis stations to an existing facility. Therefore, neither of the two ESRD need methodologies in the 2017 SMFP are applicable to the 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 relocate four dialysis stations from FMC Four Oaks to FMC Stallings Station, both in Johnston County. According to the January 2017 SDR, Table B, there is a deficit of six dialysis stations in Johnston County. After the proposed relocation of four dialysis stations from FMC Four Oaks, there will still be a deficit of six dialysis stations in Johnston County. The applicant adequately demonstrates that the proposal will not result in a greater deficit or surplus in the number of dialysis stations in Johnston County as a result of the proposed project. Therefore, the application is conforming to Policy ESRD-2.

Conclusion

In summary, the applicant adequately demonstrates that the application is consistent with Policy ESRD-2. Therefore, the application is conforming to this criterion.

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

C

BMA d/b/a FMC Stallings Station proposes to relocate four dialysis stations from FMC Four Oaks to FMC Stallings Station for a total of 28 certified dialysis stations at FMC Stallings Station and 18 certified dialysis stations at FMC Four Oaks upon project completion.

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.

In Section C-8, page 21, the applicant provides the historical patient origin for FMC Stallings Station in-center (IC), home hemodialysis (HH) and peritoneal dialysis (PD) patients as of December 31, 2016, which is summarized in the following table:

FMC STALLINGS STATION as of December 31, 2016				
County of Residence	IC Patients	HH Patients	PD Patients	Percent In-Center
Johnston	72	3	9	92.3%
Harnett	0	0	2	0.0%
Wake	5	0	3	6.4%
Other States	1	0	0	1.3%
TOTAL	78	3	14	100.0%

In Section C-1, page 16, the applicant provides the projected patient origin for FMC Stallings Station for the first two years of operation following completion of the project as follows:

FMC STALLINGS STATION								
	OPERATING YEAR 1 CY2019			OPERATING YEAR 2 CY2020			COUNTY PATIENTS AS A PERCENT OF TOTAL IN-CENTER	
	IN- CENTER	HH PATIENTS	PD PATIENTS	IN- CENTER	HH PATIENTS	PD PATIENTS	YEAR 1	YEAR 2
Johnston	85.6	3.4	10.2	89.2	3.54	10.61	90.8%	91.2%
Harnett	0.0	0.0	2.0	0.0	2.0	2.0	1.8%	1.8%
Wake	5.0	0.0	3.0	5.0	0.0	3.0	7.3%	7.1%
TOTAL	90.6	3.4	15.2	94.0	3.54	15.61	100.0%	100.0%

As shown in the table above, as of December 31, 2016, the applicant served one patient from out of state. However, the applicant does not project to serve any patients from other states in the proposed project.

The applicant provides the assumptions and methodology used to project patient origin on pages 16-18. The applicant adequately identifies the population to be served.

Analysis of Need

In Section C-2, page 18, the applicant describes the need for the proposed project as follows:

“BMA has projected a patient population of 90.6 rounded down to 90 in-center patients, to be dialyzing at the FMC Stallings Station facility at the end of the first year. Failure to add these stations will lead to higher utilization rates at the facility. Utilization by 90 patients on 28 dialysis stations is calculated to be 3.2143 patients per station, or 82.14% utilization.

The patient population projected to utilize the FMC Stallings Station facility indeed has a need for the stations at this location. The need of this population for the proposed services is a function of the individual patient need for dialysis care and treatment.”

In Section C, pages 22-23, the applicant states that the need for additional stations at FMC Stallings Station is based on the following factors:

- To provide additional dialysis care and treatment at a location that is closer and more convenient to patients (page 22).
- FMC Stallings Station currently operates 24 dialysis stations with one station being dedicated to home hemodialysis training and support. The remaining 23 stations operated with a census of 78 patients (at the time the application was submitted). This was a utilization of 84.78% or 3.39 patients per station per week (78patients / 23 stations = 3.39/4=0.8478 or 84.78%) (page 22).
- FMC Stallings Station opened in 2011 and has essentially doubled its in-center patients census from 39 (2011) patients to 78 patients 2016). During the same period of time the in-center patient census at FMC Four Oaks decreased from 63 patients to 58 patients (page 23).
- The applicant provides the in-center patient census for its facilities operated in Johnston County as of December 31, 2010 through December 31, 2016 on page 23, as illustrated below.

Facility	December 31						
	2010	2011	2012	2013	2014	2015	2016
FMC Stallings Station	NA	39	49	52	68	71	78
BMA Johnston	76	84	78	81	62	85	94
FMC Four Oaks	63	57	56	54	64	56	58

As illustrated above, FMC Stallings Station has experienced a compound annual growth rate (CARG) of 14.87% over the past five years while FMC Four Oaks has experienced a negative growth of -1.37% during the same timeframe.

- The applicant reports on page 23, that the FMC Four Oaks facility has stations which are underutilized.
- The applicant states the population growth experienced by Johnston County is occurring in the western part of the county closer to the Wake County line.

Projected In-center Utilization

The applicant projects that Operating Years One (OY1) and Operating Years Two (OY2) for the proposed project will be Calendar Year (CY) 2019 and CY2020, respectively. In Section C-1, page 17, the applicant provides its methodology for projecting IC utilization as follows:

FMC STALLINGS STATION IN-CENTER OY1 & OY2 CY2019 & CY2020	
In-center Methodology:	
BMA begins with the facility census of Johnson County patients as of December 31, 2016.	72
BMA projects this census forward one year to December 31, 2017.	$(72 \times .042) + 72 = 75$
BMA projects this census forward for one year to December 31, 2018.	$(75 \times .042) + 75 = 78.2$
Add the 4 Johnston County patients projected to transfer their care to FMC Stallings Station.	$78.2 + 4 = 82.2$
Add 5 patients from Wake County. This is the starting census for the proposal.	$82.2 + 5 = 87.2$
BMA projects this Johnston County patient population forward for 12 months to December 31, 2019.	$(82.2 \times .042) + 82.2 = 85.6$
Add the patients from Wake County. This is the end of OY1.	$85.6 + 5 = 90.6$
BMA projects this Johnston County patient population forward for 12 months to December 31, 2020.	$(85.6 \times .042) + 85.6 = 89.2$
Add patients from Wake County. This is the ending census for Operating Year 2.	$89.2 + 5 = 94.2$

In Section C-1, pages 16-17, the applicant states its in-center assumptions as follows:

1. *BMA assumes that the FMC Stallings Station patient population comprised of Johnston County residents ... will continue to increase at a rate commensurate with the Johnston*

County Five Year Average Annual Change Rate [AACR] as published in the January 2017 SDR. That rate is 4.2%.

- 2. As of December 31, 2016, the facility was serving one patient from “Other States”. BMA assumes that patient is a transient patient and will not continue dialysis at the facility. This patient is not carried forward in projections of future patient populations of the facility.*
- 3. The facility was also serving patients from Harnett (PD) and Wake Counties (in-center). BMA assumes these patients were dialyzing at the facility by patient choice. These patients are assumed to continue dialysis at the facility. BMA will add these patients to future projections at appropriate points in time.*
- 4. BMA has included five letters of support from Johnston County dialysis patients, currently dialyzing at either BMA Johnston. BMA assumes four patients will transfer their care to FMC Stallings Station upon completion of the project.*
- 5. The proposal is planned for completion by December 31, 2018.*
...”

The applicant rounds down to the nearest whole number. Therefore, the applicant projects to serve 90 in-center patients or 3.2 patients per station per week ($90/28 = 3.2142$) by the end of OY1 with a utilization rate of 80.0% ($3.2/4 = 0.8$ or 80%) and 94 in-center patients or 3.35 patients per station per week ($94/28 = 3.3571$) with a utilization rate of 83.8% ($3.35/4 = 0.8375$ or 83.8%) by the end of OY2 for the proposed facility. This satisfies 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).

In this application, the applicant assumes a projected annual rate of growth of 4.2% for the Johnston County dialysis patient census, which is consistent with the Johnston County Five Year Average Annual Change Rate (2011-2015 – Source: January 2017 SDR). The applicant states it rounded the calculation of patients down to the whole patient. Exhibit C-1 contains copies of letters, dated March 10, 2017, from five in-center patients who are currently receiving dialysis services at FKC Johnston and who are expressing support for the proposed project and their intention to consider utilizing the FMC Stallings Station facility. The five in-center patients who provided the letters of support in Exhibit C-1 identify themselves as residents of Johnston County.

Home Hemodialysis and Peritoneal Dialysis Utilization

The applicant currently provides HH and PD treatment. In Section C-8, page 21, the applicant provides historical utilization for HH and PD. In Section C-1, page 18, the applicant provides the projected utilization for HH and PD and the assumptions and methodology used to project utilization.

Projected utilization for in-center, home hemodialysis and peritoneal dialysis is based on reasonable and adequately supported assumptions regarding continued growth.

Access

In Section L-1(a), pages 54-55, the applicant states that each of BMA's 108 facilities in 42 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-7, page 58, the applicant provides the historical payor mix for FMC Stallings Station. In FY 2016, the applicant reports that 84% of its total patients at FMC Stallings Station had some or all of their services paid for by Medicare or Medicaid. Form C, pages 77-78, shows the applicant projects that 86% of the projected in-center patients will have some or all of their services paid for by Medicare or Medicaid in OY1. The applicant adequately demonstrates the extent to which all residents, including underserved groups, will have access to the proposed services.

Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for four additional stations at FMC Stallings Station, and demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the services proposed. Therefore, the application is conforming to this criterion.

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

C

The applicant proposes to relocate four existing dialysis stations from FMC Four Oaks to FMC Stallings Station for a total of 28 certified dialysis stations at FMC Stallings Station and 18 certified dialysis stations at FMC Four Oaks upon project completion.

In Section D-1, pages 26-27 of the application, the applicant provides the assumptions used to project FMC Four Oaks' utilization as of December 31, 2018. The applicant discusses how it will continue to meet the needs of dialysis patients at FMC Four Oaks after the relocation of four stations to the FMC Stallings Station facility.

The applicant's assumptions are summarized as follows:

- BMA proposes to relocate four stations from FMC Four Oaks to FMC Stallings Station. Projections begin with the FMC Four Oaks census on December 31, 2016.
- FMC Four Oaks does not provide home dialysis. The facility was serving the 58 in-center patients as of December 31, 2016.

FMC Four Oaks Patient Origin	December 31, 2016 Patient Census
Johnson	57
Sampson	1
TOTAL	51

- BMA projects growth of the Johnston County patients at the Johnston County Five Year Average Annual Change Rate of 4.2%. No growth is applied to the patient residing in Sampson County dialyzing at FMC Four Oaks. The patient from Sampson County will be added when necessary.
- BMA will subtract the four stations (effective December 31, 2018) that are relocating to FMC Stallings Station.

FMC Four Oaks	
BMA begins with the Johnston County patient census as of December 31, 2016.	57
BMA projects this census forward for one year to December 31, 2017.	$(57 \times .042) + 57 = 59.4$
BMA projects this census forward for one year to December 31, 2018.	$(59.4 \times .042) + 59.4 = 61.9$
BMA adds the 1 patient from Sampson County.	$61.9 + 1 = 62.9$
Projected Census for December 31, 2018	63

According to the January 2017 SDR, FMC Four Oaks had 58 in-center patients dialyzing on 22 certified stations, as of June 30, 2016, for a utilization of 65.91% or 2.63 patients per week per station. With the proposed relocation of four dialysis stations to FMC Stallings Station, the applicant proposes to serve 63 in-center dialysis patients or 3.5 patients per station per week ($63/18 = 3.5$) with a utilization of 87.5% ($3.5/4 = 0.875$) by December 31, 2018 at FMC Four Oaks.

Conclusion

The applicant demonstrates that the needs of the population presently served at FMC Four Oaks will continue to be adequately met following the proposed relocation of four dialysis stations to FMC Stallings Station and that access for medically underserved groups will not be negatively impacted.

Therefore, the application is conforming to this criterion.

- (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 28, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

- Maintain the status quo - The applicant states that maintaining the status quo is not an effective alternative because of the increase in patient population dialyzing with BMA.

Failure to expand the facility could result in a lack of capacity at FMC Stallings Station and an inability to accept admissions. Therefore, this alternative was rejected.

- Relocation of stations from BMA Johnston – The applicant states this facility was approved to add six stations because of its increasing census. Therefore, this alternative was rejected.

After considering the above alternatives, the applicant states that it has chosen the most efficient and cost effective alternative to meet the needs of its patients.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative. In summary, the applicant adequately demonstrates that the proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions.

1. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Stallings Station shall materially comply with all representations made in the certificate of need application.**
 2. **Bio-Medical Applications of North Carolina, Inc. shall relocate no more than four dialysis stations from FMC Four Oaks to FMC Stallings Station for a total of no more than 28 certified stations which shall include any home hemodialysis training or isolation stations.**
 3. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Stallings Station shall install plumbing and electrical wiring through the walls for no more than four additional dialysis stations, for a total of no more than 28 dialysis stations, which shall include any isolation or home hemodialysis stations.**
 4. **Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify four dialysis stations at FMC Four Oaks for a total of no more than 18 dialysis stations at FMC Four Oaks upon completion of this project.**
 5. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Stallings Station shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section 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.

The applicant proposes to relocate four existing dialysis stations from FMC Four Oaks to FMC Stallings Station, both in Johnston County, for a total of 28 dialysis stations at FMC Stallings Stations and 18 certified dialysis stations at FMC Four Oaks, upon project completion.

Capital and Working Capital Costs

In Section F-1, page 31, the applicant projects \$1,798,137 in capital costs to develop the proposed project. In Sections F.10-F.12, page 34, the applicant states that no start-up expenses and initial operating expenses are required because FMC Stallings Station is an existing facility.

Availability of Funds

In Section F-2, page 32, the applicant states it will finance the capital costs with accumulated reserves/owner’s equity of Fresenius Medical Care Holdings, Inc. (FMCH).

Exhibit F-1 contains a letter dated March 15, 2017, from the Senior Vice President and Treasurer for FMCH, the parent company of BMA, which authorizes and commits cash reserves for the project capital costs of \$1,798,137 for development of this project. Exhibit F-2 contains the Consolidated Financial Statements for FMCH which indicates that it had \$249.3 million in cash and cash equivalents as of December 31, 2015, \$19.3 in total assets and \$10.1 in net assets (total assets less total liabilities). The applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project.

Financial Feasibility

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

FMC STALLINGS STATION		
	Operating Year 1 CY2018	Operating Year 2 CY2019
Total Treatments*	12,004	13,041
Total Gross Revenues (Charges)	\$62,643,504	\$65,008,388
Total Net Revenue	\$4,050,452	\$4,203,410
Total Operating Expenses (Costs)	\$3,431,424	\$3,554,355
Net Income	\$619,027	\$649,055

*Adjusted by the applicant for missed treatments.

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. 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.

Conclusion

In summary, the applicant adequately demonstrates that sufficient funds will be available for the capital and working capital needs of the project. Furthermore, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

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

C

The applicant proposes to relocate four dialysis stations from FMC Four Oaks to FMC Stallings Station for a total of 24 certified dialysis stations at FMC Stallings Station and 18 certified dialysis stations at FMC Four Oaks upon project completion.

On page 369, 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.

There are currently three dialysis facilities in Johnston County, all of which are operated by the applicant, as illustrated below.

JOHNSON COUNTY DIALYSIS FACILITIES EXISTING & APPROVED CERTIFIED STATIONS & UTILIZATION as of June 30, 2016				
Dialysis Facility/Owner	Certified Stations 6/30/2016	# In-center Patients	Percent Utilization	Patients/ Station
FMC Four Oaks	22	58	65.91%	2.6364
FMC Stallings Station	24	74	77.08%	3.0833
Johnston Dialysis Center	25	90	90.00%	3.6000

Source: January 2017 SDR.

As shown in the table above, only Johnston Dialysis Center (aka BMA Johnston) operated above 80% utilization (3.2 patients per station per week) with a utilization of 90% or 3.6 patients per station per week. FMC Four Oaks operated with over 65% utilization and FMC Stallings Station operated with over 75% utilization. It should be noted that Johnston Dialysis Center was approved for six additional dialysis stations in Project I.D. # J-11230-16 for a total of 31 certified dialysis stations upon project completion.

The applicant provides reasonable projections for the patient population it proposes to serve in Section C, pages 16-19 of the application. The growth projections are based on a projected 4.2% average annual growth rate in Johnston County residents. At the end of the first operating

year following project completion, FMC Stallings Station projects the in-center utilization will be 3.2 in-center patients per station (90 patients / 28 dialysis stations = 3.2142), which is 80.4% of capacity. The applicant does not propose to increase or decrease the number of certified stations in the service area. The applicant adequately demonstrates the need to relocate four existing dialysis stations to FMC Stallings Station from FMC Four Oaks.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved dialysis stations or facilities. Therefore, the application is conforming to this criterion.

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

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In Section H-1, page 41, the applicant provides the current and proposed staffing for the facility. The applicant currently has 19.90 full-time equivalent (FTE) staff at the facility and proposes to add 3.50 FTE new staff as a result of this project, for a total of 23.40 FTEs. In Section H-3, pages 41-42, the applicant describes its experience and process for recruiting and retaining staff. In Section I-3, page 45, the applicant identifies the medical director as Sejan Patel, M.D., and Exhibit I-5 contains a copy of a letter dated March 7, 2017 from Dr. Patel expressing support for the proposed project. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

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

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In Section I-1, page 44, the applicant includes a list of providers of the necessary ancillary and support services. Exhibits I-2, 3 and 4 contain documentation for laboratory, hospital and transplant services, respectively. Exhibit I-5 contains a letter from the medical director of the facility describing the facility's established relationships with other healthcare providers. The applicant discusses coordination with the existing health care system on pages 45-47. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. Therefore, 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

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

NA

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

NA

- (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-1, pages 54-55, the applicant states that BMA has a long history of providing dialysis services to the underserved populations of North Carolina. FMC, BMA's parent company, currently operates 108 facilities in 42 North Carolina Counties, including affiliations with RRI facilities. The applicant further states it is policy to provide all services to all patients regardless of income, racial/ethnic origin,

gender, physical or mental conditions, age, ability to pay or any other factor which would classify a patient as underserved. On page 55, the applicant states:

“BMA of North Carolina has 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. For example, Medicare (includes Medicare Advantage treatments) represented 80.5% of North Carolina dialysis treatments in BMA facilities in FY 2016; Medicaid treatments represented an additional 5.3% of treatments in BMA facilities for FY 2016.”

In Section L-7, page 58, the applicant provides a table indicating that 84.17% of the in-center patients who received treatments at FMC Stallings Station in CY2016 had some or all of their services paid for by Medicare or Medicaid.

FMC STALLINGS STATION	
HISTORICAL PAYOR SOURCE (CY2016)	PERCENT OF TOTAL IN-CENTER PATIENTS
Self-Pay/Indigent/Charity	0.47%
Medicare	66.04%
Medicaid	4.8%
Commercial Insurance	13.85%
Medicare/Commercial	13.33%
Medicare/ Medicaid	0.00%
Miscellaneous incl. VA	1.49%
Total	100.00%

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**
2014 Estimate	2014 Estimate	2014 Estimate	2014 Estimate	2010-2014	2010-2014	2014 Estimate
Johnston	12%	51%	31%	15%	10%	19%
Wake	10%	51%	39%	12%	5%	14%
Statewide	15%	51%	36%	17%	10%	15%

Source: <http://www.census.gov/quickfacts/table>, 2014 Estimate as of December 22, 2015.

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

***This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable.”

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consists of North Carolina, South Carolina and Georgia. IPRO SA Network 6 provides

a 2015 Annual Report which includes aggregate ESRD patient data from all three states. However, a comparison of the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report*¹ percentages for North Carolina and the aggregate data for all three states in IPRO SA Network 6 shows very little variance; therefore the statistics for IPRO SA Network 6 are representative of North Carolina.

The IPRO SA Network 6 provides prevalence data on dialysis patients by age, race, and gender in its 2015 annual report, pages 27-28². 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).

The applicant adequately demonstrates that it currently provides access to medically underserved populations. Therefore, the application is conforming to this criterion.

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

C

In Section L-3(c), page 56, 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 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 57, the applicant states there have been no civil rights access complaints filed within the last five years. Therefore, 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

¹<http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf>

²http://esrd.ipro.org/wp-content/uploads/2016/11/2015_NW-6_Annual-Report_Final-Draft-with-COR-Changes-Submitted-11-29-2016.pdf

In Section L-1, page 55, the applicant projects that 85.87% of the patients who will receive in-center treatments at FMC Stallings Station will have some or all of their services paid for by Medicare or Medicaid. The table below shows the projected (CY2019) payor sources for the facility for in-center patients; which is slightly different from the historical payor source at the FMC Stallings Station facility:

FMC STALLINGS STATION	
PROJECTED PAYOR SOURCE (OY2) (CY2020)	PERCENT OF TOTAL IN-CENTER PATIENTS
Private Pay	0.46%
Commercial Insurance	11.83%
Medicare	65.83%
Medicaid	5.05%
Miscellaneous incl. VA	1.85%
Medicare Commercial	14.99%
Total	100.00%

In Section L, page 55, the applicant provides the assumptions used to project payor mix. The applicant's projected payment sources in Section L are consistent with the facility's projected (CY2020) payment sources in Section R, Form C, page 78. The applicant demonstrates that medically underserved groups will have adequate access to the services offered at FMC Stallings Station. Therefore, the application is conforming to this criterion.

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

C

In Section L-4, page 57, the applicant describes the range of means by which a person will have access to the dialysis services at FMC Stallings Station, including referrals from nephrologists. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to dialysis services. Therefore, the application is conforming to this criterion.

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

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In Section M-1, page 59, the applicant states that FMC Stallings Station has established communications with local community training programs. Exhibit M-1 contains a copy of correspondence to an area health professional training program (Johnston Community College) expressing an interest on the part of the applicant to offer the facility as a clinical training site. The information provided is reasonable and adequately supports a determination that 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.

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The applicant proposes to relocate four dialysis stations from FMC Four Oaks to FMC Stallings Station for a total of 28 certified dialysis stations at FMC Stallings Station upon project completion.

On page 369, 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.

There are currently three dialysis facilities in Johnston County, all of which are operated by the applicant, as illustrated below.

JOHNSON COUNTY DIALYSIS FACILITIES EXISTING & APPROVED CERTIFIED STATIONS & UTILIZATION as of June 30, 2016				
Dialysis Facility/Owner	Certified Stations 6/30/2016	# In-center Patients	Percent Utilization	Patients/ Station
FMC Four Oaks	22	58	65.91%	2.6364
FMC Stallings Station	24	74	77.08%	3.0833
Johnston Dialysis Center	25	90	90.00%	3.6000

Source: January 2017 SDR.

As shown in the table above, only Johnston Dialysis Center (aka BMA Johnston) operated above 80% utilization (3.2 patients per station per week) with a utilization of 90% or 3.6 patients per station per week. FMC Four Oaks operated with over 65% utilization and FMC Stallings Station operated with over 75% utilization. It should be noted that Johnston Dialysis Center was approved for six additional dialysis stations in Project I.D. # J-11230-16 for a total of 31 certified dialysis stations upon project completion.

In Section N-1, page 60, the applicant discusses how any enhanced competition would have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states:

“BMA does not expect this proposal to have effect on the competitive climate in Johnston County. BMA does not project to serve dialysis patients currently being served by another provider. The projected patient population for the FMC Stallings Station facility begins with patients currently served by BMA at other BMA locations within the county, and a growth of that patient population consistent with the Johnston County five year average annual change rate of 4.2% as published within the January 2017 SDR.

According to the January 2017 SDR there were three dialysis facilities operating within Johnston County. At this time, BMA is the sole provider of dialysis services within Johnston County. The BMA facilities offer 71 (plus six stations recently approved, CON not yet issued) dialysis stations to the ESRD patients of Johnston County. BMA seeks the opportunity to continue providing dialysis care and treatment to the patients of the area who are already choosing dialysis at a BMA facility.”

See additional information in Section N, as well as Sections A, B, C, D, E, F, G, H, I, K, L, and O where the applicant discusses the impact of the project on cost-effectiveness, quality and/or access.

The information in the application is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on the cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need for the project and that it is a cost-effective alternative. The discussions regarding the analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates it will continue providing quality services. The discussions regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicant demonstrates that it will provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (3), (3a) and (13) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

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

In Section O-3, pages 64-66, and referenced Exhibits, the applicant identifies two kidney disease treatment centers located in North Carolina, owned and operated by the applicant, that were cited in the past 18 months for deficiencies in compliance with 42 CFR Part 494, the Centers for Medicare and Medicaid (CMS) Conditions for Coverage of ESRD facilities. In Section O-3, page 66, the applicant states that both facilities are back in compliance with CMS Guidelines as of the date of submission of this application. Exhibits O-3 and O-4 contain copies of letters documenting that the facilities were determined to be back in compliance by the Centers for Medicare and Medicaid Services and the Division of Health Service Regulation. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. The application is conforming to this criterion.

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

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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.*
- NA- The applicant is not proposing to establish a new facility in this application.
- .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-1, page 16, the applicant projects to serve 90 in-center patients by the end of OY1, which is 3.2 patients per station per week ($90/28 = 3.2142$) and a utilization of 80.0% ($3.2/4 = 0.8$ or 80%). The discussion regarding projected utilization 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 16-19, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.