

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 3, 2016

Findings Date: June 3, 2016

Project Analyst: Jane Rhoe-Jones

Team Leader: Lisa Pittman

Project ID #: Q-11141-16

Facility: Greenville Dialysis Center

FID #: 944657

County: Pitt

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

Project: Add 10 dialysis stations for a total of 51 stations upon completion of this project and the following two projects: Project ID #L-11011-15 (relocate 4 stations to FMC Tarboro) and Project ID #Q-10315-14 (relocate 3 stations to FMC Farmville – certified February 28, 2016)

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 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. d/b/a Greenville Dialysis Center (“the applicant”) proposes to add ten dialysis stations for a total of 51 stations at Greenville Dialysis Center upon completion of this project and the following two projects: Project ID #L-11011-15 (relocate 4 stations to FMC Tarboro) and Project ID #Q-10315-14 (relocate 3 stations to FMC Farmville – is complete and was certified on February 28, 2016 – see Exhibit A3 for a copy of the certification letter). Greenville Dialysis Center also provides home hemodialysis (HH) and peritoneal (PD) dialysis services.

**Need Determination**

The 2016 State Medical Facilities Plan (2016 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2016 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of two dialysis stations in Pitt County; thus the applicant cannot apply to add additional stations based on the county need methodology. However, an applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. The applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate reported for Greenville Dialysis Center in the January 2016 SDR is 3.5 patients per station, or 87.5% (3.5 / 4 patients per station = 0.875). This utilization rate was calculated based on 168 in-center dialysis patients and 48 certified dialysis stations (168 patients / 48 stations = 3.5 patients per station).

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

<b>GREENVILLE DIALYSIS CENTER APRIL 1 REVIEW- JANUARY SDR</b>		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/15		87.50%
Certified Stations		48
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>48</b>
In-Center Patients as of 6/30/15 (SDR2)		168
In-Center Patients as of 12/31/14 (SDR1)		145
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	23
	Multiply the difference by 2 for the projected net in-center change	46
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/14	0.3172
(ii)	Divide the result of step (i) by 12	0.0264
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/15 until 12/31/15)	0.1586
(iv)	Multiply the result of step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	194.6483
(v)	Divide the result of step (iv) by 3.2 patients per station	60.8276
	and subtract the number of certified and pending stations to determine the number of stations needed	<b>13</b>

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is thirteen stations. Step (C) of the facility need methodology states, “*The facility may apply to expand to meet the need established ..., up to*

*a maximum of ten stations.*” The applicant proposes to add ten new stations, therefore the application is consistent with the facility need determination for dialysis stations.

### **Policies**

There is one policy in the 2016 SMFP which is applicable to this review. POLICY GEN-3: BASIC PRINCIPLES on page 39 of the 2016 SMFP is applicable to this review because the facility need methodology is applicable to this review. Policy GEN-3 states:

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

### **Promote Safety and Quality**

The applicant describes how it believes the proposed project would promote safety and quality in Section B-4(a), pages 12-13 and B-4(d), page 15, Section O, page 59-64, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

### **Promote Equitable Access**

The applicant describes how it believes the proposed project would promote equitable access in Section B-4(b), pages 13-14 and B-4(d), page 15, Section C 3, pages 21-22, Section L, pages 52-56 and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

### **Maximize Healthcare Value**

The applicant describes how it believes the proposed project would maximize healthcare value in Section B-4(c), pages 14-15 and B-4(d), page 15, Section F, pages 28-37, and Section N, page 58. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

## **Conclusion**

In summary, the applicant adequately demonstrates that the proposal is consistent with the facility need methodology in the January 2016 SDR and Policy GEN-3. 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

The applicant proposes to add ten new stations at Greenville Dialysis Center, an existing facility located at 510 Paladin Drive in Greenville. Upon completion of this project and the following two projects: Project ID #L-11011-15 (relocate 4 stations to FMC Tarboro) and Project ID #Q-10315-14 (relocate 3 stations to FMC Farmville – is complete and was certified on February 28, 2016 – see Exhibit A3 for a copy of the certification letter), Greenville Dialysis Center will be certified for 51 dialysis stations. Greenville Dialysis Center also provides home hemodialysis (HH) and peritoneal (PD) dialysis services.

## **Population to be Served**

On page 369, the 2016 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining North Carolina counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Pitt County. Facilities may also serve residents of counties not included in their service area.

In Section C-8, page 23, the applicant identifies the population served at Greenville Dialysis Center as of December 31, 2015, as illustrated below in the table:

<b>GREENVILLE DIALYSIS CENTER PATIENT ORIGIN DECEMBER 31, 2015</b>			
<b>County</b>	<b># In-Center Patients</b>	<b># Home Hemo Patients</b>	<b># PD Patients</b>
Pitt	146	7	28
Beaufort	8	0	0
Bertie	1	0	2
Chowan	1	0	2
Craven	1	0	1
Edgecombe	2	0	0
Green	2	1	1
Hertford	0	1	0
Hyde	1	0	0
Jones	0	1	0
Lenoir	1	0	3
Martin	5	2	2
Nash	0	1	1
Perquimans	0	0	1
Tyrrell	0	0	1
Washington	1	0	0
Wayne	2	0	1
Wilson	0	3	1
Other States	3	0	0
<b>TOTAL</b>	<b>174</b>	<b>16</b>	<b>44</b>

In Section C-1, page 18, the applicant identifies the patient population it proposes to serve during the first two years of operation following completion of this project and the following two projects: Project ID #L-11011-15 (relocate 4 stations to FMC Tarboro) and Project ID #Q-10315-14 (relocate 3 stations to FMC Farmville – is complete and was certified on February 28, 2016), as illustrated below in the table:

<b>GREENVILLE DIALYSIS CENTER</b>								
<b>TOTAL PROJECTED PATIENTS by COUNTY of RESIDENCE</b>								
County	OY 1 CY 2017			OY2 CY 2018			County Patients as % of Total	
	In-center	Home Hemo	PD	In-center	Home Hemo	PD	OY1	OY2
Pitt	139.9	7.7	30.6	146.3	8.0	32.0	78.1%	78.8%
Beaufort	8.0	0.0	0.0	8.0	0.0	0.0	3.5%	3.4%
Bertie	1.0	0.0	2.0	1.0	0.0	2.0	1.3%	1.3%
Chowan	1.0	0.0	2.0	1.0	0.0	2.0	1.3%	1.3%
Craven	1.0	0.0	1.0	1.0	0.0	1.0	0.9%	0.8%
Edgecombe	2.0	0.0	0.0	2.0	0.0	0.0	0.9%	0.8%
Green	2.0	1.0	1.0	2.0	1.0	1.0	1.8%	1.7%
Hertford	0.0	1.0	0.0	0.0	1.0	0.0	0.4%	0.4%
Hyde	1.0	0.0	0.0	1.0	0.0	0.0	0.4%	0.4%
Jones	0.0	1.0	0.0	0.0	1.0	0.0	0.4%	0.4%
Lenoir	1.0	0.0	3.0	1.0	0.0	3.0	1.8%	1.7%
Martin	5.0	2.0	2.0	5.0	2.0	2.0	3.9%	3.8%
Nash	0.0	1.0	1.0	0.0	1.0	1.0	0.9%	0.8%
Perquimans	0.0	0.0	1.0	0.0	0.0	1.0	0.4%	0.4%
Tyrrell	0.0	0.0	1.0	0.0	0.0	1.0	0.4%	0.4%
Washington	1.0	0.0	0.0	1.0	0.0	0.0	0.4%	0.4%
Wayne	2.0	0.0	1.0	2.0	0.0	1.0	1.3%	1.3%
Wilson	0.0	3.0	1.0	0.0	3.0	1.0	1.8%	1.7%
<b>TOTAL</b>	<b>164.9</b>	<b>16.7</b>	<b>46.6</b>	<b>171.3</b>	<b>17.0</b>	<b>48.0</b>	<b>100.0%</b>	<b>100.0%</b>

OY - Operating Year. CY - Calendar Year. Hemo - Hemodialysis. PD - Peritoneal Dialysis.

The applicant provides the assumptions and methodology for the projections above on pages 18-20.

The applicant adequately identifies the population it proposes to serve.

**Analysis of Need**

In Section B-4, page 12, the applicant states the need for the proposed project is based on the facility need methodology. The discussion regarding the need determination found in Criterion (1) is incorporated herein by reference.

*Projected Utilization: In-center*

The applicant projects to serve 164 in-center dialysis patients at the end of the first operating year, which is 3.22 patients per station per week or an 80.5% utilization rate.

In Section C-1, pages 18-20, the applicant provides the assumptions and methodology used to project in-center utilization, which are summarized below.

- The applicant assumes that Greenville Dialysis Center’s patient population will increase at Pitt County’s Five Year Average Annual Change Rate (AACR) of 4.6% (published in the January 2016 SDR).

- The applicant assumes that Greenville Dialysis Center patients from other counties will continue to dialyze at the facility. The applicant does not project increases in this patient population.
- The applicant assumes that dialysis patients from other states were transient patients and is not including these patients in future projections.
- In the certificate of need (CON) application for FMC Farmville, Project ID# Q-10315-14, the applicant projected 19 patients from Greenville Dialysis Center to transfer to the new Farmville facility. The applicant maintains this representation in this application. The Farmville facility was certified two weeks before this application was submitted; therefore the applicant subtracts 19 patients from the projected in-center census of Greenville Dialysis Center for December 31, 2016.
- OY1 is Calendar Year 2017
- OY2 is Calendar Year 2018

*In-center Methodology*

<b>GREENVILLE DIALYSIS CENTER</b>	
BMA begins with the facility census of Pitt County patients as of December 31, 2015 (ESRD Data Collection Forms, February 2016).	146
BMA projects this census forward for 12 months to December 31, 2016.	$(146 \times .046) + 146 = 157.7$
BMA subtracts 19 patients projected to transfer to Farmville	$157.7 - 19 = 133.7$
BMA projects this census forward for 12 months to December 31, 2017.	$(133.7 \times .046 + 133.7 = 139.9$
BMA adds the 25 patients residing in other counties. This is the projected ending census for Operating Year 1.	$139.9 + 25 = 164.9$
BMA projects the Pitt County patient population forward for one year to December 31, 2018.	$(139.9 \times .046) + 139.9 = 146.3$
BMA adds the 25 patients residing in other counties. This is the projected ending census for Operating Year 2.	$146.3 + 25 = 171.3$

As shown above, at the end of OY1 (2017), the applicant projects an in-center patient census of 164 patients, which is a utilization rate of 80.4% or 3.22 patients per station per week at the end of OY1. At the end of OY2 (2018), the applicant projects an in-center patient census of 171 patients, which is a utilization rate of 83.8% or 3.35 patients per station per week.

The projected utilization of 3.22 patients per station per week for OY1 satisfies the 3.2 in-center patients per station per week as required by 10A NCAC 14C .2203(b).

The applicant adequately demonstrates that projected utilization is based on reasonable and adequately supported assumptions regarding continued growth in the dialysis patient population in Pitt County.

### Home Hemodialysis

The applicant currently provides home hemodialysis (HH) and projects census to grow at the Pitt County AACR of 4.6%. See Section C, pages 20-21 for the applicant's discussion of its HH services.

### Peritoneal Dialysis

The applicant currently provides peritoneal dialysis (PD) and projects this census to grow at the Pitt County AACR of 4.6%. See Section C, pages 20-21 for the applicant's discussion of its PD services.

### Access

In Section L-1, page 52, the applicant states:

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

In Section L, page 56, the applicant provides its historical payor mix which indicates that Medicare and Medicaid represented 80.76% of all dialysis services in CY2015. The applicant confirms that low income and medically underinsured persons will continue to have access to all services provided by BMA and that the facility will conform to all federal, state and local codes and standards for handicapped access.

The applicant adequately demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services.

### Conclusion

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need that population has for the proposed project and the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services. 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.



NA

- (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.1, page 27, 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 due to the lack of capacity at the facility to meet the need of patients choosing to dialyze at the Greenville Dialysis Center facility.
- Apply for Fewer Stations – The applicant states it considered applying for fewer than ten stations but rejected the alternative because of the projected level of utilization for the Greenville Dialysis Center facility.
- Patient Transfers – Even accounting for the 19 patients projected to transfer to FMC Farmville, the projections of future utilization at the Greenville Dialysis Center facility indicate the facility will meet the required performance standards of 10A NCAC 14C .2203 and justify applying for ten dialysis stations.

After considering those alternatives, the applicant states the alternative to add ten dialysis stations as represented in the application is the most effective alternative to meet the identified need.

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 Greenville Dialysis Center shall materially comply with all representations made in the certificate of need application.**
2. **Bio-Medical Applications of North Carolina, Inc. d/b/a Greenville Dialysis Center shall develop and operate no more than ten additional dialysis stations for a total of no more than 51 certified stations upon completion of this project, and the following two projects: Project ID #L-11011-15 (relocate 4 stations to FMC Tarboro) and Project ID #Q-10315-14 (relocate 3 stations to FMC Farmville – is complete and was certified on February 28, 2016); which shall include any isolation or home hemodialysis stations.**
3. **Bio-Medical Applications of North Carolina, Inc. d/b/a Greenville Dialysis Center 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.

**C**

In Section A.6(b), page 3 and Section F.1, page 30, the applicant states that it projects no capital costs to develop this project. In Section F.10-F.12, pages 32-33, the applicant states there will be no start-up expenses or initial operating expenses incurred for this project.

**Availability of Funds**

As discussed above, the applicant states there are no capital costs required for this project. Exhibit F-1 contains a letter dated March 15, 2016 from the Senior Vice President & Treasurer for Fresenius Medical Care Holdings, Inc. (FMCH), the parent company for the applicant, which confirms no capital expenditure is required for the proposed project. Exhibit F-2 contains the Consolidated Financial Statements for FMCH which indicate that it had \$195 million in cash and cash equivalents as of December 31, 2014. The applicant adequately demonstrates that sufficient funds are available if capital needs were required for the project.

**Financial Feasibility**

In Section R, page 72-80, the applicant provides pro forma financial statements with assumptions 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 below in the table.

<b>GREENVILLE DIALYSIS CENTER</b>		
	<b>CY2017</b>	<b>CY2018</b>
Total Net Revenue	\$14,163,175	\$14,726,811
Total Operating Expenses	\$10,677,896	\$11,065,924
Net Income	\$3,485,279	\$3,660,887

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See the financial section 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**

In summary, the applicant adequately demonstrates that sufficient funds will be available for the 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, Greenville Dialysis Center, proposes to add ten dialysis stations for a total of 51 certified dialysis stations upon completion of this project and the following two projects: Project ID #L-11011-15 (relocate 4 stations to FMC Tarboro) and Project ID #Q-10315-14 (relocate 3 stations to FMC Farmville – is complete and was certified on February 28, 2016 – see Exhibit A3 for a copy of the certification letter). Greenville Dialysis Center also provides home hemodialysis (HH) and peritoneal (PD) dialysis services.

On page 369, the 2016 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining North Carolina counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Pitt County. Facilities may also serve residents of counties not included in their service area.

BMA is the sole provider of dialysis services in Pitt County and currently operates three dialysis centers. The applicant has one center under development. The applicant’s current and proposed ESRD facilities in Pitt County are shown below in the table.

<b>EXISTING AND APPROVED PITT COUNTY DIALYSIS FACILITIES</b>			
<b>Dialysis Facility</b>	<b>Certified Stations 6/30/15</b>	<b>% Utilization</b>	<b>Patients Per Station</b>
Greenville Dialysis Center	48	87.0%	3.5
FMC Dialysis Services East Carolina	38	92.76%	3.7
FMC Ayden	16	92.19%	3.7
FMC Farmville*	0	NA	NA
Source: January 2016 SDR, Table A. *FMC Farmville : the new 10-station facility was certified on February 29, 2016 (Project ID# Q-10315-14)			

As shown in the table above, the three Pitt County dialysis facilities are operating above 80% utilization (3.2 patients per station).

Greenville Dialysis Center proposes to add ten in-center dialysis stations for a total of 51 dialysis stations upon project completion. Greenville Dialysis Center was serving 168 patients weekly on 48 stations, which is 3.5 patients per station or 87.5% of capacity, as of June 30, 2015. Dialysis facilities that operate four shifts per week (2 per day on alternate days) have a capacity of four patients per station. The applicant does not propose to establish a new facility. The applicant provides reasonable projections for the in-center patient population it proposes to serve in Section C, pages 19-20 of the application. The growth projections are based on a projected 4.6% average annual growth rate in the number of Pitt County dialysis patients at the

Greenville Dialysis Center facility. At the end of Operating Year Two, Greenville Dialysis Center projects the utilization will be 3.4 in-center patients per station (171 patients / 51 dialysis stations = 3.35), which is 83.8% of capacity. The applicant adequately demonstrates the need to develop ten additional dialysis stations at the existing facility based on the number of in-center patients it proposes to serve.

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.

C

In Section H.1, page 40, the applicant provides the current staffing for the facility, which includes 39.95 full-time equivalents (FTE), and the proposed staffing for the facility following completion of the project. The applicant proposes to add 2.75 FTEs for total staffing of 42.70 FTEs upon project completion. In Section H.3, page 41, the applicant describes its experience and process for recruiting and retaining staff, and states that it does not anticipate difficulties in hiring the required staff for this project. Exhibit I-6 contains a copy of a letter from William T. Kendrick, M.D., Medical Director for the facility expressing his support for the 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.

C

In Section I.1, page 43, the applicant includes a list of providers of the necessary ancillary and support services. Exhibit I-6 contains a letter from the medical director of the facility expressing his support for the proposed project. 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.7, page 56, the applicant reports that 82.6% of the in-center patients who received treatments at Greenville Dialysis Center had some or all of their services paid for by Medicare or Medicaid in CY2015. The table below shows the historical (CY2015) payment source for the facility for in-center patients:

<b>GREENVILLE DIALYSIS CENTER HISTORICAL IN-CENTER PAYOR MIX CY 2015</b>	
<b>Payment Source</b>	<b>In-Center</b>
Self Pay/Indigent/Charity	2.17%
Commercial Insurance	9.97%
Medicare	72.81%
Medicaid	3.19%
Misc. (includes VA)	5.21%
Medicare Commercial Insurance	6.64%
<b>Total</b>	<b>100.00%</b>

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

<b>Percent of Population</b>						
<b>County</b>	<b>% 65+</b>	<b>% Female</b>	<b>% Racial &amp; Ethnic Minority*</b>	<b>% Persons in Poverty**</b>	<b>% &lt; Age 65 with a Disability</b>	<b>% &lt; Age 65 without Health Insurance**</b>
Pitt	11%	53%	44%	23%	8%	18%
Beaufort	22%	52%	34%	19%	14%	20%
Bertie	20%	50%	65%	28%	14%	17%
Chowan	22%	52%	39%	23%	10%	18%
Craven	17%	49%	34%	16%	13%	17%
Edgecombe	17%	54%	63%	26%	13%	17%
Greene	15%	46%	52%	28%	15%	22%
Hertford	18%	51%	66%	26%	16%	17%
Hyde	18%	45%	39%	22%	10%	23%
Jones	22%	51%	38%	22%	17%	22%
Lenoir	18%	52%	50%	22%	17%	19%
Martin	21%	53%	48%	20%	12%	17%
Nash	16%	52%	48%	18%	11%	17%
Perquimans	24%	52%	29%	17%	14%	17%
Tyrrell	19%	46%	47%	28%	12%	25%
Washington	21%	53%	55%	27%	18%	17%
Wayne	15%	51%	46%	23%	12%	18%
Wilson	16%	53%	52%	24%	11%	20%
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 *Southeastern Kidney Council Network 6 Inc. Annual Report* provides prevalence data on North Carolina dialysis patients by age, race, and gender on page 59, summarized as follows:

<b>Number and Percent of Dialysis Patients by Age, Race, and Gender 2014</b>		
	<b># of ESRD Patients</b>	<b>% of Dialysis Population</b>
<b>Age</b>		
0-19	52	0.3%
20-34	770	4.8%
35-44	1,547	9.7%
45-54	2,853	17.8%
55-64	4,175	26.1%
65+	6,601	41.3%
<b>Gender</b>		
Female	7,064	44.2%
Male	8,934	55.8%
<b>Race</b>		
African-American	9,855	61.6%
White	5,778	36.1%
Other, inc. not specified	365	2.3%

Source: <http://www.esrdnetwork6.org/utills/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older and over 63% were non-Caucasian. (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59*).

- (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(e), page 54, 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 Section L.6, page 55, 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

In Section L.1(b), page 53, the applicant projects that 82.6% of the in-center patients who will receive treatments at Greenville Dialysis Center in the second operating year (CY2018) will have some or all of their services paid for by Medicare or Medicaid. The table below shows the projected Year 2 payment source for the facility for in-center patients:

<b>GREENVILLE DIALYSIS CENTER IN-CENTER CY2018</b>	
<b>Payment Source</b>	<b>In-Center</b>
Private Pay	2.17%
Commercial Insurance	9.97%
Medicare	72.81%
Medicaid	3.19%
VA	5.21%
Medicare Commercial Insurance	6.64%
<b>Total</b>	<b>100.00%</b>

In Section L.1, pages 52-53, the applicant provides the assumptions used to project payor mix. The applicant's projected payment sources are consistent with the facility's historical (CY2015) payment sources as reported by the applicant in Section L.7, page 56. The applicant demonstrates that medically underserved groups will have adequate access to the services offered at Greenville Dialysis Center. 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 55, the applicant describes the range of means by which a person will have access to the dialysis services at Greenville Dialysis Center, including referrals from nephrologists, other physicians, or hospital emergency rooms. 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.

C



In Section M.1, page 57, the applicant states that Greenville Dialysis Center has established relationships with local community training programs, and the applicant will continue to offer the same opportunities to local health professional training programs. Exhibit M-1 contains a copy of correspondence to an area health professional training program expressing an interest on the part of the applicant to offer the facility as 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.

## C

The applicant, Greenville Dialysis Center, proposes to add ten dialysis stations for a total of 51 certified dialysis stations upon completion of this project and the following two projects: Project ID #L-11011-15 (relocate 4 stations to FMC Tarboro) and Project ID #Q-10315-14 (relocate 3 stations to FMC Farmville – is complete and was certified on February 28, 2016 – see Exhibit A3 for a copy of the certification letter). Greenville Dialysis Center also provides home hemodialysis (HH) and peritoneal (PD) dialysis services.

On page 369, the 2016 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining North Carolina counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Pitt County. Facilities may also serve residents of counties not included in their service area.

BMA is the sole provider of dialysis services in Pitt County and currently operates three dialysis centers in the county. The applicant has one center under development. The applicant's current and approved ESRD facilities in Pitt County are shown below in the table.

<b>PITT COUNTY EXISTING and APPROVED DIALYSIS FACILITIES</b>			
<b>Dialysis Facility</b>	<b>Certified Stations 6/30/15</b>	<b>% Utilization</b>	<b>Patients Per Station</b>
Greenville Dialysis Center	48	87.5%	3.5
FMC Dialysis Services East Carolina	38	92.76%	3.7
FMC Ayden	16	92.19%	3.7
FMC Farmville*	0	NA	NA
Source: January 2016 SDR, Table A. *FMC Farmville - new 10 station facility was certified on February 29, 2016 (Project ID# Q-10315-14)			

As shown in the table above, the three Pitt County dialysis facilities are operating above 80% utilization (3.2 patients per station).

In Section N.1, page 58, the applicant discusses how its services have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states,

*“BMA facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid. The majority of our patients rely upon Medicare and Medicaid to cover the expense of their treatments. In this application, BMA projects that greater than 82% of the In-center treatments will be reimbursed by government payors (Medicare/Medicaid/VA). The facility must capitalize upon every opportunity for efficiency.*

*BMA facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients. ... This proposal will certainly not adversely affect quality, but rather, enhance the quality of the ESRD patients’ lives by offering another convenient venue for dialysis care and treatment.”*

See also Sections B, C, E, F, G, H and L where the applicant discusses the impact of the project on cost-effectiveness, quality and 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 provide quality services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- The applicant demonstrates that it will provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (1) 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.

C

In Exhibit A-4, the applicant identifies the kidney disease treatment centers located in North Carolina owned and operated by the applicant or an affiliated company. In Section O.3, pages 63-64, the applicant identifies two of its facilities, BMA Lumberton and BMA East Charlotte, 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. The applicant states both facilities are back in full compliance with CMS Guidelines as of the date of submission of this application. 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.

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.*

-NA- Greenville Dialysis Center is an existing facility.

- .2203(b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*
- C- In Section C.1, pages 19-20, the applicant projects to serve 164 in-center patients by the end of Operating Year 1, which is 3.2 patients per station ( $164 / 51 = 3.2$ ). 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 18-20, the applicant provides the assumptions and methodology used to project in-center patient utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.