

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 21, 2016

Findings Date: June 21, 2016

Project Analyst: Gregory F. Yakaboski

Team Leader: Fatimah Wilson

Project ID #: F-11139-16

Facility: FMC Lincolnton

FID #: 944237

County: Lincoln

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

Project: Add 3 dialysis stations for a total of 28 dialysis stations upon completion of this project

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a FMC Lincolnton (“the applicant”) proposes to add three dialysis stations for a total of 28 certified dialysis stations at the FMC Lincolnton facility upon completion of this project.

#### **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

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January 2016 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of two dialysis stations in Lincoln County, thus the applicant cannot apply to add any 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 FMC Lincoln in the January 2016 SDR is 3.36 patients per station per week, or 84.0% (3.36 / 4 patients per station = 0.84 or 84.0%). This utilization rate was calculated based on 84 in-center dialysis patients and 25 certified dialysis stations (84 patients / 25 stations = 3.36 patients per station per week).

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

<b>APRIL 1 REVIEW-JANUARY SDR</b>		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/15		84.00%
Certified Stations		25
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>25</b>
In-Center Patients as of 6/30/15 (SDR2)		84
In-Center Patients as of 12/31/14 (SDR1)		79
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	5
	Multiply the difference by 2 for the projected net in-center change	10
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/14	0.1266
(ii)	Divide the result of step (i) by 12	0.0105
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/15 until 12/31/15)	0.0633
(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	89.3165
(v)	Divide the result of step (iv) by 3.2 patients per station	27.9114
	and subtract the number of certified and pending stations to determine the number of stations needed	<b>3</b>

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is three 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 three 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, pages 12-13 and 15-16 and Section O, pages 59-62. 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, pages 13-14, Section C, page 21, Section I, pages 42-45, 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, pages 14-16, Section N, page 58, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need as identified by the applicant. Therefore, the application is consistent with Policy GEN-3.

**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

BMA proposes to add three dialysis stations for a total of 28 certified dialysis stations at the FMC Lincolnton facility upon completion of this project. FMC Lincolnton does not have a home therapies program nor are they proposing one in this project.

**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 Lincoln County. Facilities may also serve residents of counties not included in their service area.

In Section C, page 23, the applicant provides a table showing the historical patient origin for in-center (IC) patients served by FMC Lincolnton, as shown below:

**Dialysis Patients as of 12/312015**

COUNTY	IC PATIENTS
Lincoln	65
Gaston	13
Catawba	8
Total	86

In Section C, page 19, the applicant identifies the patient population it proposes to serve during the first two years of operation following project completion, as illustrated in the table below:

COUNTY	OPERATING YEAR 1 CY2017			OPERATING YEAR 2 CY2018			COUNTY PATIENTS AS % OF TOTAL	
	IC	HH	PD	IC	HH	PD	OY 1	OY 2
Lincoln	73.4	0	0	78	0	0	75.6%	75.6%
Gaston	14.7	0	0	16	0	0	15.1%	15.1%
Catawba	9.0	0	0	10	0	0	9.3%	9.3%
Total	97.2	0	0	103.3	0	0	100.0%	100.0%

The applicant provides the assumptions and methodology for the projections above on pages 19-21.

The applicant adequately identifies the population it proposes to serve.

**Analysis of Need**

The applicant proposes to add three dialysis stations to the existing FMC Lincolnton facility for a total of 28 certified dialysis stations upon project completion. In Section C, pages 20-21, the applicant states the need for the proposed project is based on the following factors:

- ESRD patients require dialysis treatment on a regular and consistent basis in order to maintain life.
- Failure to add the three proposed stations will lead to higher utilization rates at the existing facility.
- FMC Lincolnton census has been increasing at a rate greater than the Five-Year Average Annual Change Rate for: Lincoln County- (-2.9%); Gaston County- (3.5%); and Catawba County- (2.6%). The applicant states that the Facility Need Methodology calculates a growth rate of (12.7%) for this facility (See application page 20). As of June 30, 2014, FMC Lincolnton had 78 in-center patients and as of June 30, 2015 FMC Lincolnton had 86 in-center patients which represents a growth rate for the overall patient population of the facility of approximately 10.5% over the last year. [1.105 x 78 = 86.19]
- BMA applies a growth rate of 6.3% to the patient population (comprised of residents of Lincoln, Gaston and Catawba Counties) of the FMC Lincolnton facility which constitutes only half of the growth of the facility census for the last year.
- The needs of the patient population projected to utilize the proposed service is a function of individual patient need for dialysis care and treatment.

Projected Utilization

In Section C, page 19, the applicant provides projected utilization during the first two years of operation following project completion, as illustrated in the table below:

	OPERATING YEAR 1 CY2017			OPERATING YEAR 2 CY2018			County Patients as a % of total	
	IC	HH	PD	IC	HH	PD	OY1	OY2
Lincoln	73.4	0	0	78	0	0	75.6%	75/6%
Gaston	14.7	0	0	16	0	0	9.3%	9.3%
Catawba	9.0	0	0	16	0	0	15.1%	15.1%
Total	97.2	0	0	103.3	0	0	100.0%	100.0%

In Section C, pages 19-23, the applicant provided the assumptions and methodology utilized to project utilization. On page 20, the applicant provides a table illustrating how utilization was projected, which is summarized below:

- Operating Year 1 (CY2017) = January 1 – December 31, 2017
- Operating Year 2 (CY2018)= January 1 – December 31, 2018
- BMA assumes that the patients dialyzing at FMC Lincolnton who are residents of Gaston and Catawba County are at FMC Lincolnton by choice and will continue to dialyze at FMC Lincolnton.
- BMA does not indicate that the Five Year Average Annual Growth Rate for Lincoln, Gaston or Catawba is an appropriate growth factor for projecting future patient populations of the FMC Lincolnton facility.
- A growth rate of 6.3% was used for the entire facility patient population which constitutes only half of the growth of the facility census for the last year.

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Begin with the facility census on December 31, 2015.	86
Project this patient population forward one year to December 31, 2016.	$1.063 \times 86 = 91.4$
Project this patient population forward one year to December 31, 2017. This is the projected ending census for <b>Operating Year 1 (CY2017)</b> .	$1.063 \times 91.4 = 97.15$
Project this patient population forward one year to December 31, 2018. <b>This is the projected ending census for Operating Year 2 (CY2018)</b> .	$1.063 \times 97.15 = 103.3$

Operating Year One

The applicant demonstrates that FMC Lincolnton will serve a total of 97 in-center patients at the end of Operating Year One (CY2017) for a utilization rate of 86.6% or 3.46 patients per station per week ( $97 \text{ patients} / 28 \text{ stations} = 3.4642 / 4 = .8661$  or 86.6%). The projected utilization of 3.46 patients per station per week for Operating Year One satisfies the 3.2 in-center patients per station per week threshold as required by 10A NCAC 14C .2203(b).

Furthermore, in Section C, page 23, the applicant provided data for the FMC Lincolnton facility as of December 31, 2015 based on the ESRD Data Collection Forms submitted in February 2016 to the Healthcare Planning Section. Based on the existing 25 certified stations, the applicant demonstrates that as of December 31, 2015, the facility was operating at 86.0% or 3.4 patients per station per week ( $86 \text{ patients} / 25 \text{ stations} = 3.44 / 4 = .86$  or 86.0%). Over a two year period the applicant projects an increase of 11 in-center patients from 86 in-center patients as of December 31, 2015 to 97 in-center patients as of December 31, 2017, the end of Operating Year One.

Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth at FMC Lincolnton.

**Access**

In Section L, pages 52-53, the applicant states that each of BMA’s 104 facilities in 42 North Carolina counties has a patient population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, and other underserved persons. The table below shows the historical payment sources of the facility for CY2015:

<b>Payment Source</b>	<b>Percent of Total Patients</b>
Private Pay	0.38%
Commercial Insurance	3.97%
Medicare	75.77%
Medicaid	4.02%
Miscellaneous (Incl. VA)	7.55%
Other: Medicare/Commercial Insurance	8.31%

The applicant projects 88.1% of its patients will be Medicare or Medicaid recipients in CY2018. The applicant adequately demonstrates the extent to which all residents of the service area, including underserved groups, are likely to have access to its services.

**Conclusion**

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need that population has for the services proposed 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 discusses the alternatives considered prior to submitting this application, which include:

1. Maintain the Status Quo - the applicant states that this option would result in higher utilization rates and potentially restrict patient admissions at FMC Lincolnnton.
2. Apply for fewer stations – The Facility Need calculations and the growth of the patient population demonstrated the need for three additional stations at the FMC Lincolnnton facility.

3. Add home therapies- The physical plant does not have the requisite space to add home therapies.

After considering the above alternatives, the applicant believes the most cost effective alternative is to add three stations to ensure adequate access for the patients of FMC Lincolnton.

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 this 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 Lincolnton shall materially comply with all representations made in the certificate of need application.**
  - 2. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Lincolnton shall develop and operate no more than three additional dialysis stations at FMC Lincolnton for a total of no more than 28 certified dialysis stations which shall include any isolation or home hemodialysis training stations upon completion of this project.**
  - 3. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Lincolnton shall install plumbing and electrical wiring through the walls for no more than three additional dialysis stations, which shall include any isolation or home hemodialysis training stations.**
  - 4. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Lincolnton shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

BMA proposes to add three dialysis station for a total of 28 certified dialysis stations at the FMC Lincolnton facility upon completion of this project.

**Capital and Working Capital Costs**

In Section F, page 29, the applicant projects the capital cost for the proposed project, as summarized in the table below:

(RO) water treatment equipment	\$2,500
Equipment/furniture not included above	\$11,350
<b>Total</b>	<b>\$13,600</b>

In Section F, pages 32-33, the applicant states that there are no working capital needs for the proposed project since FMC Lincolnton is an existing facility.

**Availability of Funds**

In Section F, pages 30-31, the applicant states that accumulated reserves will be used to finance the proposed project. In Exhibit F-1 the applicant provides a letter dated March 15, 2016, from Mark Fawcett, Senior Vice President & Treasurer, Fresenius Medical Care Holdings, Inc., which is the parent of National Medical Care, Inc. and Bio-Medical Applications of North Carolina, Inc. The letter confirms that he is authorized to commit cash reserves, which he does in the amount of \$13,600 for the proposed project.

Exhibit F-2 contains a copy of Fresenius Medical Care Holdings, Inc. and Subsidiaries (FMC) Consolidated Financial Statements for December 31, 2014. As of December 31, 2014, FMC had \$195,280,000 in cash and cash equivalents, \$18,507,042,000 in total assets and \$8,428,400,000 in net assets (total assets less total liabilities). (See Exhibit F-2, page 3)

The applicant adequately demonstrated that sufficient funds will be available for the capital needs of the project.

**Financial Feasibility**

In the projected revenue and expense statement in Section R, Form B, the applicant projects revenues will exceed operating expenses in both of the first two operating years following completion of the proposed project, as shown in the table below.

<b>FMC LINCOLNTON REVENUE AND EXPENSES - TOTAL FACILITY</b>		
	<b>OPERATING YR 1 CY 2017</b>	<b>OPERATING YR 2 CY 2018</b>
Gross Patient Revenue	\$55,552,840	\$59,102,160
Deductions from Gross Patient Revenue	\$51,547,057	\$54,840,443
Net Patient Revenue	\$4,005,783	\$4,261,717
Operating Expenses	\$3,798,856	\$3,950,773
<b>Net Income</b>	<b>\$206,928</b>	<b>\$310,944</b>

The assumptions used by the applicant in preparation of the pro formas are reasonable including projected utilization, costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of costs and charges.

**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

BMA proposes to add three dialysis stations for a total of 28 certified dialysis stations at the FMC Lincolnton facility upon completion of this project.

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 Lincoln County. Facilities may also serve residents of counties not included in their service area.

FMC Lincolnton is the only dialysis center in Lincoln County. There are no other providers of dialysis services in Lincoln County.

**Lincolnton County Dialysis Facilities**

<b>Dialysis Facility</b>	<b>Certified Stations 6/30/2015</b>	<b>% Utilization</b>	<b>Patients Per Station</b>
FMC Lincolnton	25	84.0%	3.3600

Source: January 2015 SDR, Table A.

As shown in the table above, based on the most recent SDR, FMC Lincolnton was operating at 84.0% utilization as of June 30, 2015.

Furthermore, in Section C, page 23, the applicant provided data for the FMC Lincolnton facility as of December 31, 2015 based on the ESRD Data Collection Forms submitted in February 2016 to the Healthcare Planning Section. Based on the existing 25 certified stations, the applicant demonstrates that as of December 31, 2015, the facility was operating at 86.0% or 3.4 patients per station per week (86 patients/ 25 stations = 3.44 / 4 = .86 or 86.0%). Over a two year period the applicant projects an increase of 11 in-center patients from 86 in-center patients as of December 31, 2015 to 97 in-center patients as of December 31, 2017, the end of Operating Year One.

In Section C, pages 19-23, the applicant demonstrates that FMC Lincolnton will serve a total of 97 in-center patients at the end of Operating Year One (CY2017) for a utilization rate of 86.6% or 3.46 patients per station per week (97 patients / 28 stations = 3.4642 / 4 = .8661 or 86.6%). The projected utilization of 3.46 patients per station per week for Operating Year One satisfies the 3.2 in-center patients per station per week threshold as required by 10A NCAC 14C .2203(b).

The applicant states that the projected utilization rates are based on patients currently dialyzing at FMC Lincolnton.

The applicant adequately demonstrates the need to add three additional station at FMC Lincolnton based on the number of in-center patients it proposes to serve. The discussion on analysis of need found in Criterion (3) is incorporated herein by reference.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities in Lincoln County. Consequently, 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, page 38, the applicant provides the following table to illustrate current and projected staffing in full time equivalents (FTEs) for FMC Lincolnnton. The applicant states the Medical Director is not employed by the facility, and thus is not reflected on the staffing chart.

POSITION	CURRENT # FTEs	# FTEs TO BE ADDED	PROJECTED # FTEs
Registered Nurse	4.00	0.50	4.50
Technician (PCT))	10.00	1.00	11.00
Clinical Manager	1.00		1.00
Director of Operations	0.15		0.15
Dietician	1.00		1.00
Social Worker	1.00		1.00
Chief Tech	0.15		0.15
Equipment Tech	0.85	0.15	1.00
In-Service	0.15	0.05	0.20
Clerical	1.00		1.00
<b>Total</b>	<b>19.30</b>	<b>1.70</b>	<b>21.00</b>

In Section H, page 41, the applicant provides the projected direct care staff for FMC Lincolnnton in Operating Year 2, as shown below in the table:

DIRECT CARE POSITIONS	# FTEs	HOURS PER YEAR PER FTE	TOTAL ANNUAL FTE HOURS	TOTAL ANNUAL HOURS OF OPERATION	# FTE HOURS PER HOUR OF OPERATION
Registered Nurse	4.5	2,080	9360	3,120	3.00
Technician (PCT)	11.0	2,080	22880	3,120	7.33
<b>Total</b>	<b>15.5</b>	<b>4,160</b>	<b>32240</b>	<b>6,240</b>	<b>10.33</b>

In Section I, page 43, the applicant identifies Dr. Kimberly Yates as the Medical Director of the facility. In Exhibit I-6, the applicant provides a copy of a letter signed by Dr. Yates of Metrolina Nephrology Associates, PA supporting the project and confirming her commitment to serve as Medical Director. In Section H, pages 39, the applicant describes the methods used to recruit and fill vacant or new positions.

The applicant documents the availability of adequate health manpower and management personnel, including the Medical Director, for the provision of the proposed dialysis 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, page 42, 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 discusses coordination with the existing health care system on pages 43-45. Exhibits I-3 through I-5, respectively, contain copies of agreements for lab services, acute services and transplantation. 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, page 56, the applicant reports that 88.1% of the patients who received treatments at FMC Lincolnton had some or all of their services paid for by Medicare or Medicaid in the past year. The table below shows the historical payment sources of the facility in CY2015:

<b>Payment Source</b>	<b>Percent of Total Patients</b>
Private Pay	0.38%
Commercial Insurance	3.97%
Medicare	75.77%
Medicaid	4.02%
Miscellaneous (Incl. VA)	7.55%
Other: Medicare/Commercial Insurance	8.31%
<b>Total</b>	<b>100.00%</b>

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

<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>
Gaston	15%	52%	25%	17%	13%	18%
Catawba	16%	51%	23%	16%	9%	18%
Lincoln	16%	50%	15%	16%	11%	19%
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*).

The applicant demonstrates that it currently provides adequate 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;

*“BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations”* (See Section L, page 54). In Section L, page 55, the applicant states *“There have been no Civil Rights complaints lodged against any BMA North Carolina facilities in the past five years.”* The application is conforming to this criterion.

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

C

In Section L, page 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 conditions, age, ability to pay or any other factor that would classify a patient as underserved.”*

In Section L, page 53, the applicant projects that 88.1% of all patients in CY2018 who will receive dialysis treatments at FMC Lincolnton will have all or part of their services paid for by Medicare and or Medicaid, as indicated in the table below:

<b>Payment Source</b>	<b>Percent of Total Patients</b>
Private Pay	0.38%
Commercial Insurance	3.97%
Medicare	75.77%
Medicaid	4.02%
Miscellaneous (Incl. VA)	7.55%
Other: Medicare/Commercial Insurance	8.31%
<b>Total</b>	<b>100.00%</b>

The projected payor mix reflects the historical payor mix. The applicant demonstrates that medically underserved populations will have adequate access to the proposed services. 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, page 55, the applicant states,

*“Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. FMC Lincolnton has an open policy, which means that any Nephrologist may apply to admit patient to the facility. The attending physicians receive referrals from other physicians or Nephrologists or hospital emergency rooms. ... Transient patients are accepted upon proper coordination of care with the patient’s regular nephrologist and a physician with staff privileges at the facility.”*

The applicant adequately demonstrates that FMC Lincolnton will provide a range of means by which a person can access the 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, page 57 the applicant states that FMC Lincolnton has an agreement with Gaston College to serve as a facility for clinical rotations for nursing students. The project analyst notes that Exhibit M-1 does not contain a copy of an agreement between FMC Lincolnton and Gaston College however, Exhibit M-1 does contain a letter from BMA to Gaston College offering the FMC Lincolnton facility to be included in Gaston College’s list of facilities for clinical rotation of its nursing students. The information provided in Section M is reasonable and credible and supports a finding of conformity 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

BMA proposes to add three dialysis station for a total of 28 certified dialysis stations at the FMC Lincolnton facility upon completion of this project.

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 Lincoln County. Facilities may also serve residents of counties not included in their service area.

FMC Lincolnton is the only dialysis center in Lincoln County. There are no other providers of dialysis services in Lincoln County.

**Lincolnton County Dialysis Facilities**

<b>Dialysis Facility</b>	<b>Certified Stations 6/30/2015</b>	<b>% Utilization</b>	<b>Patients Per Station</b>
FMC Lincolnton	25	84.0%	3.3600

Source: January 2015 SDR, Table A.

As shown in the table above, based on the most recent SDR, FMC Lincolnton was operating at 84.0% utilization as of June 30, 2015.

Furthermore, in Section C, page 23, the applicant provided data for the FMC Lincolnton facility as of December 31, 2015 based on the ESRD Data Collection Forms submitted in February 2016 to the Healthcare Planning Section. Based on the existing 25 certified stations, the applicant demonstrates that as of December 31, 2015, the facility was operating at 86.0% or 3.4 patients per station per week (86 patients/ 25 stations = 3.44 / 4 = .86 or 86.0%). Over a two year period the applicant projects an increase of 11 in-center patients from 86 in-center patients as of December 31, 2015 to 97 in-center patients as of December 31, 2017, the end of Operating Year One.

In Section C, pages 19-23, the applicant demonstrates that FMC Lincolnton will serve a total of 97 in-center patients at the end of Operating Year One (CY2017) for a utilization rate of 86.6% or 3.46 patients per station per week (97 patients / 28 stations = 3.4642 / 4 = .8661 or 86.6%). The projected utilization of 3.46 patients per station per week for Operating Year One satisfies the 3.2 in-center patients per station per week threshold as required by 10A NCAC 14C .2203(b).

In Section N, page 58, the applicant discusses how any enhanced competition in the service area will promote 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 Lincoln County. At the present time, BMA is the only provider of dialysis services in Lincoln County. BMA does not project to serve dialysis patients currently being served by another provider. The projected patient population for the FMC Lincoln facility begins with patients currently served by BMA, and a growth of that patient population at a rate of 6/3%; this is one half of the facility experience over the last year.”*

See also Sections C, F, G, H, L and P where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicant in the sections referenced above 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 proposed project and that it is an effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates that FMC Lincoln will continue to provide quality dialysis services. The discussion regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- The applicant demonstrates that FMC Lincoln will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (1), (3) 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, pages 59-64, and Exhibit O-1, the applicant discusses the methods it uses to ensure and maintain quality. On page 62 the applicant states that the FMC Lincoln facility meets the Conditions for Coverage for ESRD facilities. See also Exhibit O-2.

In Section O, pages 63-64, the applicant lists two facilities that were cited for deficiencies that resulted in a finding of Immediate Jeopardy during the 18-month look back period: BMA Lumberton and BMA East Charlotte. See the table below which shows the survey dates and the dates the facilities were found to be back in compliance with CMS.

BMA QUALITY CARE		
FACILITY	SURVEY DATE	BACK IN COMPLIANCE
BMA Lumberton	5/6/2015	Yes
BMA East Charlotte	8/11/2015	Yes

Based on a review of this certificate of need application and publicly available information, 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 Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The application is conforming or conditionally conforming to all applicable criteria, as discussed below.

**10 NCAC 14C .2203 PERFORMANCE STANDARDS**

*.2203(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the*

*performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*

-NA- This application is to add stations and does not proposed establishing a new End Stage Renal Disease facility.

*.2203(b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*

-C- In Section C, pages 19-23, the applicant demonstrates that FMC Lincolnton will serve a total of 97 in-center patients at the end of Operating Year One for a utilization rate of 86.6% or 3.46 patients per station per week ( $97 \text{ patients} / 28 \text{ stations} = 3.4642 / 4 = .8661$  or 86.6%). The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

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

-C- In Section C.1, pages 19-23, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.