

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 19, 2016

Findings Date: December 19, 2016

Project Analyst: Gregory F. Yakaboski

Assistant Chief: Martha J. Frisone

Project ID #: F-11232-16

Facility: FMC Lincolnton

FID #: 944237

County: Lincoln

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

Project: Add 2 dialysis stations for a total of 30 dialysis stations upon completion of this project and Project ID #F-11139-16 (add 3 dialysis stations)

### 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 two dialysis stations for a total of 30 certified dialysis stations at the FMC Lincolnton facility upon completion of this project and Project ID #F-11139-16 (add 3 dialysis stations).

#### **Need Determination**

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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 July 2016 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of five 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 July 2016 SDR is 3.52 patients per station per week, or 88.0% (3.52 / 4 patients per station = 0.88 or 88.0%). This utilization rate was calculated based on 88 in-center dialysis patients and 25 certified dialysis stations (88 patients / 25 stations = 3.52 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>OCTOBER 1 REVIEW-JULY SDR</b>		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/15		88.00%
Certified Stations		25
Pending Stations		3
<b>Total Existing and Pending Stations</b>		<b>28</b>
In-Center Patients as of 12/31/15 (July 2016 SDR) (SDR2)		88
In-Center Patients as of 6/30/15 (Jan 2016 SDR) (SDR1)		84
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	4
	Multiply the difference by 2 for the projected net in-center change	8
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/15	0.0952
(ii)	Divide the result of step (i) by 12	0.0079
(iii)	Multiply the result of step (ii) by 6 (the number of months from 12/31/14 until 12/31/15)	0.0952
(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	96.3810
(v)	Divide the result of step (iv) by 3.2 patients per station	30.1190
	and subtract the number of certified and pending stations to determine the number of stations needed	<b>2.1190</b>

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is two 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 two 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, 14-15, Section O, pages 56-62, 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, page 13, 14-15, Section C, page 19, Section I, pages 39-42, Section L, pages 49-53, 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 13-15, Section N, page 55, 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 July 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 two dialysis stations for a total of 30 certified dialysis stations at the FMC Lincolnton facility upon completion of this project and Project ID #F-11139-16 (add 3 dialysis stations).

FMC Lincolnton does not have a home therapies program nor are they proposing one in this project.

### **Patient Origin**

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 21, 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 6/30/2016**

COUNTY	IC PATIENTS
Lincoln	54
Gaston	20
Catawba	6
Cleveland	1
Total	81

In Section C, page 17, 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 CY2018			OPERATING YEAR 2 CY2019			COUNTY PATIENTS AS % OF TOTAL	
	IC	HH	PD	IC	HH	PD	OY 1	OY 2
Lincoln	67.9	0	0	74.3	0	0	66.7%	66.7%
Gaston	25.1	0	0	27.5	0	0	24.7%	24.7%
Catawba	7.5	0	0	8.3	0	0	7.4%	7.4%
Cleveland	1.3	0	0	1.4	0	0	1.2%	1.2%
Total	101.8	0	0	111.5	0	0	100.0%	100.0%

The applicant provides the assumptions and methodology for the projections above on pages 17-19. The applicant adequately identifies the population it proposes to serve.

**Analysis of Need**

In Section B-2, pages 9-10, 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. See also Section C-2, pages 18-19.

**Projected Utilization**

In Section C, page 17, the applicant provides projected utilization during the first two years of operation following project completion, as illustrated in the table below:

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COUNTY	OPERATING YEAR 1 CY2018			OPERATING YEAR 2 CY2019			COUNTY PATIENTS AS % OF TOTAL	
	IC	HH	PD	IC	HH	PD	OY 1	OY 2
Lincoln	67.9	0	0	74.3	0	0	66.7%	66.7%
Gaston	25.1	0	0	27.5	0	0	24.7%	24.7%
Catawba	7.5	0	0	8.3	0	0	7.4%	7.4%
Cleveland	1.3	0	0	1.4	0	0	1.2%	1.2%
Total	101.8	0	0	111.5	0	0	100.0%	100.0%

In Section C, pages 17-21, the applicant provides the assumptions and methodology used to project utilization. On pages 17-18, the applicant provides a table illustrating how utilization was projected, which is summarized below:

- Operating Year 1 (CY2018) = Calendar Year 2018
- Operating Year 2 (CY2019)= Calendar Year 2019
- BMA notes that a significant portion of the patients utilizing FMC Lincolnton are residents of Gaston, Catawba and Cleveland counties. BMA assumes they are at FMC Lincolnton by choice and will continue to dialyze at FMC Lincolnton.
- BMA states that the Five Year Average Annual Growth Rate for Lincoln County is not an appropriate growth factor for projecting utilization at the FMC Lincolnton facility because a significant portion of its patients (33.3%) are residents of other counties.
- BMA used the growth rate of 9.52% which is the annual growth rate for the facility based on the Facility Need Methodology.

The following table illustrates application of these assumptions and the methodology used.

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Begin with the facility census on June 30, 2016.	81
Project the census forward for six months to December 31, 2016 using one half of the 9.52% growth rate.	$[81 \times (0.952/12 \times 6)] + 81 = 84.9$
Project this patient population forward one year to December 31, 2017 using the 9.52% growth rate.	$1.0952 \times 84.9 = 92.98$
Project this patient population forward one year to December 31, 2018. This is the projected ending census for <b>Operating Year 1 (CY2018)</b> .*	$1.0952 \times 92.98 = 101.8$
Project this patient population forward one year to December 31, 2019. <b>This is the projected ending census for Operating Year 2 (CY2019)</b> .*	$1.0952 \times 101.8 = 111.5$

\*The table in the application includes typographical errors which have been corrected in this table.

Projected patients for OY1 and OY2 are rounded down to the nearest whole number. Therefore, at the end of OY1 (CY 2018) the facility is projected to serve 101 in-center patients and at the end of OY2 (CY2019) the facility is projected to serve 111 in-center patients.

The projected utilization rates for the first two operating years are as follows:

- OY1: 3.36 patients per station per week, or 84.2% (101 patients / 30 stations = 3.366/4 = 0.8418 or 84.2%).
- OY2: 3.7 patients per station per week, or 92.5% (111 patients / 30 stations = 3.7/4 = 0.925 or 92.5%).

The projected utilization of 3.36 patients per station per week at the end of OY1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

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

**Access**

In Section L, pages 49-50, the applicant states that each of BMA's 105 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 CY2015 payment sources of the facility and shows that 88.1% of the patients were Medicare or Medicaid recipients

<b>Payment Source- CY2015</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%
Total	100.00%

Source: Section L-7, page 53.

The applicant projects 88.49% of its patients will be Medicare or Medicaid recipients in CY2019. 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 25, 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 two additional stations at the FMC Lincolnton 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 two 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 two additional dialysis stations for a total of no more than 30 certified dialysis stations upon completion of this project and Project ID #F-11139-16 (add 3 dialysis stations), which shall include any home hemodialysis training or isolation stations.**
  - 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 two additional dialysis 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 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.

BMA proposes to add two dialysis station for a total of 30 certified dialysis stations at the FMC Lincolnnton facility upon completion of this project and Project ID #F-11139-16 (add 3 dialysis stations).

**Capital and Working Capital Costs**

In Section F, page 27, the applicant projects the capital cost for the proposed project, as summarized in the table below:

(RO) water treatment equipment	\$1,500
Equipment/furniture not included above	\$7,900
<b>Total</b>	<b>\$9,400</b>

In Section F, pages 30-31, the applicant states that there are no working capital needs for the proposed project since FMC Lincolnnton is an existing facility.

**Availability of Funds**

In Section F, pages 28-29, the applicant states that accumulated reserves will be used to finance the proposed project. In Exhibit F-1, the applicant provides a letter dated September 15, 2016, from Mark Fawcett, Senior Vice President & Treasurer, Fresenius Medical Care Holdings, Inc., which is the parent of 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 \$9,400 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, 2015. As of December 31, 2015, FMC had \$249,300,000 in cash and cash equivalents, \$19,332,539,000 in total assets and \$10,144,288,000 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</b>		
<b>REVENUE AND EXPENSES - TOTAL FACILITY</b>		
	<b>OPERATING YR 1</b>	<b>OPERATING YR 2</b>
	<b>CY 2018</b>	<b>CY 2019</b>
Gross Patient Revenue	\$57,327,500	\$62,647,492
Deductions from Gross Patient Revenue	(\$52,988,295)	(\$57,905,609)
Net Patient Revenue	\$4,339,205	\$4,741,883
Operating Expenses	(\$3,906,358)	(\$4,187,252)
<b>Net Income</b>	<b>\$432,847</b>	<b>\$554,630</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 the availability of sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based on reasonable projections of costs and charges.

In Section H, page 36, the applicant provides projected staffing and salaries. Form A in Section R, shows budgeted operating costs adequate to cover the projected staffing. The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

**Conclusion**

In summary, the applicant adequately demonstrates that sufficient funds will be available for the operating and 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 two dialysis stations for a total of 30 certified dialysis stations at the FMC Lincolnton facility upon completion of this project and Project ID #F-11139-16 (add 3 dialysis stations).

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

FMC Lincolnnton 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 12/31/2015</b>	<b>% Utilization</b>	<b>Patients Per Station</b>
FMC Lincolnnton	25	88.0%	3.5200

Source: July 2016 SDR, Table A.

As shown in the table above, based on the most recent SDR, FMC Lincolnnton was operating at 88.0% utilization as of December 31, 2016. Therefore, the facility is well utilized.

In Section C, pages 17-21, the applicant demonstrates that FMC Lincolnnton will serve a total of 101 in-center patients at the end of Operating Year One (CY2018) for a utilization rate of 84.2% or 3.36 patients per station per week (101 patients / 30 stations = 3.3666 / 4 = .8416 or 84.2%). The projected utilization of 3.36 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 adequately demonstrates that projected utilization is based on reasonable assumptions regarding growth of in-center patients at the facility. Therefore, the applicant adequately demonstrates the need to add two additional stations at FMC Lincolnnton based on the number of in-center patients it proposes to serve.

In summary, the applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved dialysis stations 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 36, 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.

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POSITION	CURRENT # FTES	# FTES TO BE ADDED	PROJECTED # FTES
Registered Nurse	4.50		4.50
Technician (PCT))	11.00	1.00	12.00
Clinical Manager	1.00		1.00
Director of Operations	0.25		0.25
Dietician	0.75		0.75
Social Worker	0.75		0.75
Chief Tech	0.15		0.15
Equipment Tech	0.85		0.85
In-Service	0.25		0.25
Clerical	1.00		1.00
<b>Total</b>	<b>20.50</b>	<b>1.0</b>	<b>21.50</b>

As illustrated in the table above, the applicant projects an increase in the total number of FTE positions at FMC Lincolnton of one (1) FTE technician position.

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 37, 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.

C

In Section I, page 39, the applicant includes a list of providers of the necessary ancillary and support services. Exhibit I-5 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 40-42. Exhibits I-1 through I-4, respectively, contain copies of agreements for home training, 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 53, 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, 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 51). In Section L, page 52, 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 49, 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 50, the applicant projects that 88.49% of all patients in CY2019 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	0.93%
Commercial Insurance	3.43%
Medicare	76.08%
Medicaid	4.01%
Miscellaneous (Incl. VA)	7.15%
Other: Medicare/Commercial Insurance	8.40%
<b>Total</b>	<b>100.00%</b>

The projected payor mix is similar to 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 patients 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 54 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 two dialysis station for a total of 30 certified dialysis stations at the FMC Lincolnton facility upon completion of this project and Project ID #F-11139-16 (add 3 dialysis stations).

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 12/31/2015</b>	<b>% Utilization</b>	<b>Patients Per Station</b>
FMC Lincolnton	25	88.0%	3.5200

Source: July 2016 SDR, Table A.

As shown in the table above, based on the most recent SDR, FMC Lincolnton was operating at 88.0% utilization as of December 31, 2016. Therefore, the facility is well utilized.

In Section N, page 55, 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 Lincolnton facility begins with patients currently served by BMA, and a growth of that patient population at a rate of 9.52%; this is equivalent to recent facility experience.”*

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 Lincolnnton will continue to provide quality dialysis services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- The applicant demonstrates that FMC Lincolnnton 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.

C

In Section B, pages 12, 14-15, and Section O, pages 56-59, and Exhibits O-1 and O-2, the applicant discusses the methods it uses to ensure and maintain quality. The FMC Lincolnnton facility meets the Conditions for Coverage for ESRD facilities. See Exhibit O-2.

In Section O, pages 59-62, the applicant lists three facilities that were cited for deficiencies that resulted in a finding of Immediate Jeopardy during the 18-month look back period: BMA Lumberton, BMA East Charlotte and RAI West College-Warsaw. See the table below and Exhibits O-2-5.

<b>BMA QUALITY CARE</b>		
<b>FACILITY</b>	<b>SURVEY DATE</b>	<b>BACK IN COMPLIANCE</b>
BMA Lumberton	5/6/2015	Yes
BMA East Charlotte	8/11/2015	Yes
RAI West College-Warsaw	3/15/2016	Yes

Based on a review of the 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- FMC Lincolnton is an existing facility.

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

-C- In Section C, pages 17-21, the applicant demonstrates that FMC Lincolnton will serve a total of 101 in-center patients at the end of Operating Year One (CY2018) for a utilization rate of 84.2% or 3.36 patients per station per week (101 patients / 30 stations = 3.3666 / 4 = .8416 or 84.2%). 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, pages 17-21, 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.