

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 8, 2016

Findings Date: June 8, 2016

Project Analyst: Gregory F. Yakaboski

Team Leader: Lisa Pittman

Project ID #: F-11140-16

Facility: FMC Belmont

FID #: 050039

County: Gaston

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

Project: Add 1 dialysis station for a total of 19 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 Belmont (“the applicant”) proposes to add one dialysis station for a total of 19 certified dialysis stations at the FMC Belmont 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 January 2016 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of one dialysis station in Gaston 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 Belmont in the January 2016 SDR is 3.8125 patients per station per week, or 95.31% ( $3.8125 / 4$  patients per station = 0.9531). This utilization rate was calculated based on 61 in-center dialysis patients and 16 certified dialysis stations ( $61$  patients /  $16$  stations = 3.8125 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		95.32%
Certified Stations		16
Pending Stations		2
<b>Total Existing and Pending Stations</b>		<b>18</b>
In-Center Patients as of 6/30/15 (SDR2)		61
In-Center Patients as of 12/31/14 (SDR1)		54
<b>Step</b>	<b>Description</b>	<b>Result</b>
(i)	Difference (SDR2 - SDR1)	7
	Multiply the difference by 2 for the projected net in-center change	14
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/14	0.2593
(ii)	Divide the result of step (i) by 12	0.0216
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/15 until 12/31/15)	0.1296
(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	68.9074
(v)	Divide the result of step (iv) by 3.2 patients per station	21.5336
	and subtract the number of certified and pending stations to determine the number of stations needed	<b>3.5336</b>

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is four 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 one new station, 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.

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BMA proposes to add one dialysis stations for a total of 19 certified dialysis stations at the FMC Belmont facility upon completion of this project. FMC Belmont does not include a home therapies program.

**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 Gaston 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 Belmont, as shown below:

**Dialysis Patients as of 12/312015**

COUNTY	IC PATIENTS
Gaston	58
Mecklenburg	7
Other States	2
Total	67

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			OPERATING YEAR 2			COUNTY PATIENTS AS % OF TOTAL	
	IC	HH	PD	IC	HH	PD	OY 1	OY 2
Gaston	62.1	0	0	64.3	0	0	89.9%	90.2%
Mecklenburg	7.0	0	0	7.0	0	0	10.1%	9.8%
Total	69.1	0	0	71.3	0	0	100.0%	100.0%

The applicant provides the assumptions and methodology for the projections above on pages 18-21.

The applicant adequately identifies the population it proposes to serve.

**Analysis of Need**

The applicant proposes to add one dialysis station to the existing FMC Belmont facility for a total of 19 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 proposed station will lead to higher utilization rates at the existing facility.
- FMC Belmont census has been increasing at a rate greater than the Five-Year Average Annual Change Rate for Gaston County of 3.5%. The applicant states that the Facility Need Methodology calculates a growth rate of 25.93% for this facility.
- 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:

COUNTY	OPERATING YEAR 1			OPERATING YEAR 2		
	IC	HH	PD	IC	HH	PD
Gaston	62.1	na	na	64.3	na	na
Mecklenburg	7.0	na	na	7.0	na	na
Total	69.1	na	na	71.3	na	na

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 = January 1 – December 31, 2017
- Operating Year 2= January 1 – December 31, 2018
- Growth rate of 3.5% for the patient population residing in Gaston County which is the Five Year Average Annual Growth Rate for Gaston County.
- No growth projected for patients from outside the service area (Mecklenburg County).

FMC Belmont  
F-11140-16  
Page 7

Begin with the Gaston County patients dialyzing at FMC Belmont as of December 31, 2015.	58
Project the Gaston County patient population forward one year to December 31, 2016.	$1.035 \times 58 = 60.0$
Project this patient population forward one year to December 31, 2017.	$1.035 \times 60.0 = 62.1$
<b>OY1:</b> Add the 7 patients currently dialyzing from Mecklenburg County. This is the projected ending census for Operating Year 1.	$62.1 + 7 = 69.1$
Project the Gaston County patient population forward one year to December 31, 2018.	$1.035 \times 62.1 = 64.3$
<b>OY2:</b> Add the patients currently dialyzing from Mecklenburg County. This is the projected ending census for Operating Year 1.	$64.3 + 7 = 71.3$

Operating Year One

The applicant demonstrates that FMC Belmont will serve a total of 69 in-center patients at the end of Operating Year One for a utilization rate of 90.8% or 3.6 patients per station ( $69 \text{ patients} / 19 \text{ stations} = 3.632 / 4 = .9078$  or 90.8%). The projected utilization of 3.6 patients per station per week for Operating Year One satisfies the 3.2 in-center patients per station threshold as required by 10A NCAC 14C .2203(b).

In Section C, page 23, the applicant provided the data for the FMC Belmont facility as of December 31, 2015. As of December 31, 2015 a total of 67 in-center patients were dialyzing at FMC Belmont. The applicant projects a total of 69 in-center patients will be dialyzing at FMC Belmont as of December 31, 2017 (Operating Year 1). There is only a difference of two (2) in-center patients between the number of in-center patients already dialyzing at FMC Belmont and the projected number of in-center patients at FMC Belmont at the end of Operating Year 1.

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

**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 applicant projects 84.8% of its patients will be Medicare or Medicaid recipients. 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 Belmont.
2. Apply to add more than one station– Although FMC Belmont qualifies for the addition of four stations per the facility need methodology, the facility does not have the physical space to accommodate more than one additional station.

After considering the above alternatives, the applicant believes the most cost effective alternative is to add one station to ensure adequate access for the patients of FMC Belmont.

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 Belmont 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 Belmont shall develop and operate no more than one additional dialysis station at FMC Belmont for a total of no more than 19 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 Belmont shall install plumbing and electrical wiring through the walls for no more than one additional dialysis station, which shall include any isolation or home hemodialysis training stations.**
  4. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Belmont 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.

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BMA proposes to add one dialysis station for a total of 19 certified dialysis stations at the FMC Belmont 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:

<b>Projected Capital Costs</b>	
(RO) water treatment equipment	\$1,000
Equipment/furniture not included above	\$4,700
<b>Total</b>	<b>\$5,700</b>

In Section F, pages 32-33, the applicant states that there are no working capital needs for the proposed project since FMC Belmont 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 Bryan Mello, Assistant 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 5,700 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 BELMONT</b>		
<b>REVENUE AND EXPENSES - TOTAL FACILITY</b>		
	<b>OPERATING YR 1 CY 2017</b>	<b>OPERATING YR 2 CY 2018</b>
Gross Patient Revenue	\$40,191,064	\$41,371,512
Deductions from Gross Patient Revenue	\$36,923,056	\$38,007,520
Net Patient Revenue	\$3,268,008	\$3,363,992
Operating Expenses	\$2,981,024	\$3,064,085
<b>Net Income</b>	<b>\$286,984</b>	<b>\$299,907</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 one dialysis station for a total of 19 certified dialysis stations at the FMC Belmont 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 Gaston County. Facilities may also serve residents of counties not included in their service area.

The applicant operates four dialysis centers in Gaston County. There are no other providers of dialysis services in Gaston County.

**Gaston County Dialysis Facilities**

<b>Dialysis Facility</b>	<b>Certified Stations 6/30/2015</b>	<b>% Utilization</b>	<b>Patients Per Station</b>
BMA Kings Mountain	14	94.64%	3.7857
FMC Belmont	16	95.31%	3.8125
FMC Gastonia	39	85.90%	3.4359
FMC South Gastonia	20	88.75%	3.5500

Source: January 2015 SDR, Table A.

As shown in the table above, based on the most recent SDR, all of the dialysis facilities in Gaston County were operating at 85.0% utilization or above.

In Section I, pages 38-39, the applicant utilized the data as of December 31, 2015 based on the ESRD Data Collection Forms submitted in February 2016 to the Healthcare Planning Section as illustrated below.

**Gaston County Dialysis Facilities**

<b>Dialysis Facility</b>	<b>Certified Stations 12/31/2015</b>	<b>% Utilization</b>	<b>Patients Per Station</b>
BMA Kings Mountain	16*	82.81%	3.3125
FMC Belmont	18*	93.06%	3.7222
FMC Gastonia	39	89.74%	3.5897
FMC South Gastonia	20	96.25%	3.8500

\*Note: that this table factors in an additional 4 stations based on approved Certificates of Need. Two in BMA Kings Mountain and two in FMC Belmont.

As shown in the table above, all four of the Gaston County dialysis facilities are operating above 80% utilization (3.2 patients per station).

In Section C, pages 19-23, the applicant demonstrates that FMC Belmont will serve a total of 69 in-center patients at the end of Operating Year One for a utilization rate of 90.8% or 3.6 patients per station (69 patients / 19 stations = 3.632 / 4 = .9078 or 90.8%). The projected utilization of 3.6 patients per station per week for Operating Year One satisfies the 3.2 in-center patients per station 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 Belmont.

The applicant adequately demonstrates the need to add three additional station at FMC Belmont 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 discussion on competition found in Criterion (18a) 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 Gaston 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.

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In Section H, page 39, the applicant provides the following table to illustrate current and projected staffing in full time equivalents (FTEs) for FMC Belmont. 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	2.5		2.5
Technician (PCT))	7.5		7.5
Clinical Manager	1.0		1.0
Administrator	0.15		0.15
Dietician	0.50		0.50
Social Worker	0.50		0.50
Chief Tech	0.15		0.15
Equipment Tech	0.60		0.60
In-Service	0.15		0.15
Clerical	1.00		1.00
<b>Total</b>	<b>14.05</b>		<b>14.05</b>

In Section H, page 41, the applicant provides the projected direct care staff for FMC Belmont 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	2.5	2,080	5,200	3,120	1.67
Technician (PCT)	7.5	2,080	15,600	3,120	5.00
<b>Total</b>	<b>10.0</b>	<b>2,080</b>	<b>20,800</b>	<b>3,120</b>	<b>6.67</b>

In Section I, page 43, the applicant identifies Dr. Douglas Nigbor as the Medical Director of the facility. In Exhibit I-6, the applicant provides a copy of a letter signed by Dr. Nigbor of Metrolina Nephrology Associates, PA supporting the project and confirming her commitment to serve as Medical Director. In Section H, pages 40, 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 84.8% of the patients who received treatments at FMC Belmont had some or all of their services paid for by Medicare or Medicaid in CY 2014. The table below shows the historical payment sources of the facility:

<b>Payment Source</b>	<b>Percent of Total Patients</b>
Commercial Insurance	8.99%
Medicare	69.99%
Medicaid	2.48%
Miscellaneous (Incl. VA)	6.20%
Other: Medicare/Commercial Insurance	12.34%
<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%
Mecklenburg	10%	52%	51%	15%	6%	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 84.8% of all patients who will receive dialysis treatments at FMC Belmont 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>
Commercial Insurance	8.99%
Medicare	69.99%
Medicaid	2.48%
VA	6.20%
Other: Medicare/Commercial Insurance	12.34%
<b>Total</b>	<b>100.00%</b>

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 Belmont 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 Belmont 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 Belmont 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 Belmont and Gaston College however, Exhibit M-1 does contain a letter from BMA to Gaston College offering the FMC Belmont 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 one dialysis station for a total of 19 certified dialysis stations at the FMC Belmont 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 Gaston County. Facilities may also serve residents of counties not included in their service area.

The applicant operates four dialysis centers in Gaston County. There are no other providers of dialysis services in Gaston County.

**Gaston County Dialysis Facilities**

<b>Dialysis Facility</b>	<b>Certified Stations 6/30/2015</b>	<b>% Utilization</b>	<b>Patients Per Station</b>
BMA Kings Mountain	14	94.64%	3.7857
FMC Belmont	16	95.31%	3.8125
FMC Gastonia	39	85.90%	3.4359
FMC South Gastonia	20	88.75%	3.5500

Source: January 2016 SDR, Table A.

As shown in the table above, based on the most recent SDR, all of the dialysis facilities in Gaston County were operating at 85.0% utilization or above.

In Section G, pages 37-38, the applicant utilized the data as of December 31, 2015 based on the ESRD Data Collection Forms submitted in February 2016 to the Healthcare Planning Section as illustrated below.

**Gaston County Dialysis Facilities**

<b>Dialysis Facility</b>	<b>Certified Stations 12/31/2015</b>	<b>% Utilization</b>	<b>Patients Per Station</b>
FMC Belmont*	18	93.06%	3.7222
BMA Kings Mountain*	16	82.81%	3.3125
FMC Gastonia	39	89.74%	3.5897
FMC South Gastonia	20	96.25%	3.8500

\*Note: that this table factors in an additional 4 stations based on approved Certificate of Needs. Two in BMA Kings Mountain and two in FMC Belmont.

As shown in the table above, all four of the Gaston County dialysis facilities are operating above 80% utilization (3.2 patients per station).

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 Gaston County. At the present time, BMA is the only provider of dialysis services in Gaston County. BMA does not project to serve dialysis patients currently being served by another provider. The projected patient population for the FMC Belmont facility begins with patients currently served by BMA, and a growth of that patient population consistent with the Gaston County five year average annual change rate of 3.5% as published within the January 2016 SDR. ”*

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 Belmont will continue to provide quality dialysis services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicant demonstrates that FMC Belmont will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (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 Belmont 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 Belmont will serve a total of 69 in-center patients at the end of Operating Year One for a utilization rate of 90.8% or 3.6 patients per station (69 patients / 19 stations = 3.632 / 4 = .9078 or 90.8%). 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.