

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: May 5, 2015

Findings Date: May 5, 2015

Project Analyst: Gloria C. Hale

Team Leader: Lisa Pittman

Project ID #: F-11008-15

Facility: FMC South Gaston

FID #: 070531

County: Gaston

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

Project: Add six dialysis stations for a total of 26 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. d/b/a FMC South Gaston proposes to add six dialysis stations for a total of 26 certified dialysis stations upon completion of this project.

#### Need Determination

The 2015 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2015 Semiannual Dialysis Report (SDR), the county need methodology shows there is no need for an additional facility in Gaston County. However, 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 South Gaston in the January 2015 SDR is 3.65 patients per station. This utilization rate was calculated based on 73 in-center dialysis

patients and 20 certified dialysis stations as of June 30, 2014 (73 patients / 20 stations = 3.65 patients per station). Application of the facility need methodology indicates that six additional stations are needed for this facility, as illustrated in the following table:

**2015 SMFP Facility Need Methodology**

Required SDR Utilization		80%
FMC South Gaston Utilization Rate as of 6/30/2014		91.25%
Certified Stations		20
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>20</b>
In-Center Patients as of 12/31/2013 (SDR1, July 2014 SDR)		65
In-Center Patients as of 6/30/2014 (SDR2, January 2015 SDR)		73
Step	Description	
(i)	Difference (SDR2 - SDR1)	8
	Multiply the difference by 2 for the projected net in-center change	16
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/2013	.2462
(ii)	Divide the result of Step (i) by 12	.0205
(iii)	Multiply the result of Step (ii) by 6 (the number of months from 6/30/2014 until December 31, 2014) for the January 2015 SDR	.1230
(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	81.9790
(v)	Divide the result of Step (iv) by 3.2 patients per station and subtract the number of certified and pending stations as recorded in SDR2 to determine the number of stations needed	5.6184

As shown in the table above, based on the facility need methodology for dialysis stations, which allows for rounding to the nearest whole number only in step (v), the potential number of stations needed at FMC South Gaston is six. 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 only six new stations and, therefore, is consistent with the facility need determination for dialysis stations.

**Policies**

*Policy GEN-3: Basic Principles*, page 38, of the 2015 SMFP 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, a subsidiary of Fresenius Medical Care Holdings, Inc., describes how its proposal will promote safety and quality in Section I, pages 4-8, and Section II, pages 12, 19-20, and 26-29. 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 will promote equitable access in Section II, pages 15, 21-22, Section VI.1, pages 45-47, and referenced exhibits. The applicant states in Section II, pages 21-22, that the majority of its dialysis patients are covered by Medicare and/or Medicaid and projects that greater than 89% of its in-center dialysis treatments will be covered by Medicare or Medicaid. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal will promote equitable access.

#### Maximize Healthcare Value

The applicant describes how it believes the proposed project will maximize health care value for resources expended in Section II, page 21, and Section V, page 44. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal will maximize healthcare value.

#### Conclusion

The applicant adequately demonstrates that the proposal is consistent with *Policy GEN-3: Basic Principles* and adequately demonstrates that the application is consistent with the facility need determination in the January 2015 SDR. 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

Bio-Medical Applications of North Carolina, Inc. d/b/a FMC South Gaston, whose parent company is Fresenius Medical Care Holdings, Inc. (FMC), proposes to add six dialysis stations to its existing facility for a total of 26 certified dialysis stations upon completion of the proposed project.

**Population to be Served**

In Section III.7, page 34, the applicant identifies the patient population it proposes to serve for the first two years of operation following project completion, as illustrated in the following table.

County	Operating Year 1 CY 2017	Operating Year 2 CY 2018	County Patients as Percent of Total	
	In-Center	In-Center	Year 1	Year 2
Gaston	77.6	83.6	88.59%	89.32%
Mecklenburg	1.0	1.0	1.14%	1.07%
South Carolina	9.0	9.0	10.27%	9.61%
<b>Total</b>	<b>87.6</b>	<b>93.6</b>	<b>100.00%</b>	<b>100.00%</b>

The applicant adequately identifies the population to be served.

**Need Analysis**

The applicant proposes to add six dialysis stations to FMC South Gaston for a total of 26 stations upon completion of this project, pursuant to the 2015 SMFP Facility Need Methodology.

In Section III.7, pages 31-33, the applicant provides the following assumptions used to project utilization:

As of June 30, 2014, as reported in the January 2015 SDR, the utilization rate at FMC South Gaston was 91.25% or 3.65 patients per station per week based on 73 in-center patients utilizing 20 certified dialysis stations.

The applicant projects that the growth rate for FMC South Gaston will exceed the Gaston County Five Year Average Annual Change Rate (AACR) of 0.3% as reported

in the January 2015 SDR. Based on a review of the utilization rates for FMC South Gaston published in the January SDRs over the past five years, the applicant states that the Five Year AACR for the facility was 15.55%, as illustrated below:

SDR	Jan. 2011	Jan. 2012	Jan. 2013	Jan. 2014	Jan. 2015	<b>Five Year Average Annual Change Rate</b>
Census Date	6/30/2010	6/30/2011	6/30/2012	6/30/2013	6/30/2014	
	43	57	71	62	73	
Change		14	14	-9	11	
% Change		0.3256	0.2456	-0.1268	0.1774	0.1555

The applicant utilizes a growth rate of 7.77% “*in an effort to offer more conservative estimates of the future patient population*” of FMC South Gaston to project the number of in-center patients from Gaston County only, in operating years one and two. The applicant does not assume any growth in the number of in-center patients from Mecklenburg County or South Carolina. However, the applicant does assume that the existing patients from Mecklenburg County and South Carolina will continue to receive dialysis services at FMC South Gaston. Operating Year One is projected to be CY 2017 and Operating Year Two is projected to be CY 2018.

In Section III.7, page 33, the applicant provides the following methodology used to project utilization:

<b>FMC South Gaston</b>	<b>In-Center</b>
Beginning facility census of Gaston County patients, December 31, 2014	62
Project Gaston County patient population forward one year to December 31, 2015 using a 7.77% growth rate	$(62 \times .0777) + 62 = 66.8$
Project Gaston County patient population forward one more year to December 31, 2016, the date of projected project completion	$(66.8 \times .0777) + 66.8 = 72.0$
Add 10 patients from Mecklenburg County and South Carolina who are expected to continue dialyzing at FMC South Gaston. This is the beginning census for this project.	$72.0 + 10 = 82.0$
Project the Gaston County population forward one year to December 31, 2017 using a 7.77% growth rate	$(72.0 \times .0777) + 72.0 = 77.6$
Add 10 patients from Mecklenburg County and South Carolina who are expected to continue to dialyze at FMC South Gaston. This is the ending census for Operating Year One.	$77.6 + 10 = 87.6$
Project the Gaston County population forward one year to December 31, 2018 using the 7.77% growth rate	$(77.6 \times .0777) + 77.6 = 83.6$
Add the 10 patients from Mecklenburg County and South Carolina who are expected to continue to dialyze at FMC South Gaston. This is the ending census for Operating Year Two.	$83.6 + 10 = 93.6$

The applicant states, in Section III, page 34,

*“BMA also recognizes the CON Section has previously indicated that patients are not partial patients, but rather are whole. In financial projections and utilization projections for this application, BMA has rounded down to the whole number.”*

Therefore, for Operating Year One, the applicant projects to serve 87 in-center patients dialyzing on 26 stations for a projected utilization rate of 3.35 patients per station ( $87 \text{ in-center patients} / 26 \text{ stations} = 3.35$ ) which exceeds the minimum standard of 3.2 patients per station per week as required by 10A NCAC 14C .2203(b).

In summary, the applicant adequately identifies the population to be served and adequately demonstrates the need for six additional dialysis stations at the FMC South Gaston facility.

**Access to Services**

In Section VI, page 45, the applicant states that the parent company of Biomedical Applications of North Carolina, Inc. (BMA), Fresenius Medical Care Holdings, Inc. (FMC), currently operates 100 facilities in 42 North Carolina counties and that each of these facilities provide services to low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons. The applicant projects, in Section VI, page 46, that 90.35% of its in-center patients will be covered by either Medicare,

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

### **Conclusion**

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for six additional stations at FMC South Gaston 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 III.9, pages 36-37, the applicant discusses the alternatives considered prior to the submission of this application, summarized as follows:

1. Maintain the Status Quo – the applicant dismissed this alternative based on the fact that it does not address the growing census at FMC South Gaston and that doing nothing would *“eventually remove choice from the patient options.”*
2. Apply for Fewer than Six Stations - the applicant dismissed this alternative based on the fact that it does not address the growing patient census at FMC South Gaston or the growth at other BMA facilities in Gaston County. The applicant states that the facility is growing at a greater annual rate than the county as a whole.
3. Serve a Higher Number of Patients than Proposed – the applicant states that is could have used a higher growth rate of 9.93%, generated by calculating the Five Year AACR using the year end census data for the facility, to project the number of patients to be served. This would have resulted in a higher projected number of patients. However, the applicant chose to use *“a cost effective and conservative approach to this proposal without overstating the projections.”*

Thus, the applicant concluded that the project as proposed was the most effective alternative to meet the need.

The applicant adequately demonstrates the need for six additional dialysis stations based on the facility's projected utilization. The discussion regarding need and projected utilization found in Criterion (3) is incorporated herein by reference.

The application is conforming to all other applicable statutory and regulatory review criteria, and thus is approvable. An application that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that the proposal is its least costly or most effective alternative to meet the need. Consequently, 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 South Gaston 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 South Gaston shall develop no more than six additional stations for a total of no more than 26 certified stations upon completion of this project, which shall include any home hemodialysis or isolation stations.**
  - 3. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC South Gaston shall install plumbing and electrical wiring through the walls for no more than six additional dialysis stations for a total of no more than 26 dialysis stations upon completion of this project, which shall include any home hemodialysis or isolation stations.**
  - 4. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC South Gaston 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

In Section VIII.1, page 54, the applicant projects the total capital cost for the project will be \$479,716, including \$412,716 for a construction contract, \$25,000 for water treatment equipment, and \$42,000 for equipment and furniture.

In Section IX, page 58, the applicant projects no initial start-up costs or initial operating expenses because this is an existing facility.

In Section VIII.2, page 55, the applicant states it will fund the capital needs of the proposed project from accumulated reserves. Exhibit 24 contains a letter, dated March 16, 2015, from the Vice President of Fresenius Medical Care Holdings, Inc., which states,

*“This is to inform you that Fresenius Medical Care Holdings, Inc is the parent company of National Medical Care, Inc. and Bio-Medical Applications of North Carolina, Inc.*

*BMA is submitting a Certificate of Need Application to add six dialysis stations to its FMC South Gaston facility in Gaston County. The facility will have a total of 26 dialysis stations. The project calls for the following capital expenditure:*

*Capital Expense \$479,716*

*As Vice President, I am authorized and do hereby authorize addition of six dialysis stations, for capital costs as identified above. Further, I am authorized and do hereby authorize and commit cash reserves for the capital cost of \$479,716 as may be needed for this project.”*

In Exhibit 4, the applicant provides the Consolidated Financial Statements for Fresenius Medical Care Holdings, Inc. and Subsidiaries for the years ended December 31, 2013 and 2012. As of December 31, 2013, Fresenius Medical Care Holdings, Inc. and Subsidiaries had \$275,719,000 in cash and cash equivalents, \$16,597,314,000 in total assets and \$8,521,824,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of funds for the capital needs of the project.

In Section X.1, page 59, the applicant provides the allowable charges per treatment for each payment source, as illustrated in the table below:

**Allowable Charges**

<b>Payor</b>	<b>In-Center Charge</b>
Private Pay	\$1,425.00
Commercial Insurance	\$1,425.00
Medicare	\$239.02
Medicaid	\$140.23
Medicare/Medicaid	\$239.02
Medicare/Commercial	\$239.02
State Kidney Program	\$100.00
VA	\$231.12
Other: Self/Indigent	\$1,425.00

The applicant states, on page 59, that the commercial charge listed does not reflect actual reimbursement. In addition, the applicant states that Medicare utilizes a “‘Bundling’

*reimbursement program*”, which results in a basic rate for Medicare reimbursement, including all ancillary services, of approximately \$240 per dialysis treatment.

In Section X.3, page 61, the applicant states that to project revenues it used an average number of in-center patients, rounded down to the nearest whole number, for the first and second operating years of the project. Therefore, the number of in-center patients used in operating year one was 84 and the number of in-center patients used in operating year two was 90. In Sections X.2, page 60, and X.4, page 65, the applicant projects revenues and operating expenses as follows:

<b>FMC South Gaston</b>		
	<b>Operating Year 1</b>	<b>Operating Year 2</b>
Total Net Revenue	\$4,282,520	\$4,602,826
Total Operating Costs	\$3,567,108	\$3,779,842
<b>Net Profit</b>	<b>\$715,412</b>	<b>\$822,983</b>

The applicant projects that revenue will exceed operating expenses in each of the first two operating years of the project. The assumptions used in preparation of the pro forma financial statements, including the number of projected treatments, are reasonable and adequately supported. See Section X, pages 59-66, for the applicant’s assumptions.

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital and operating expenses of the project, and that the financial feasibility of the proposal are based on reasonable projections of revenues and operating expenses. 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 d/b/a FMC South Gaston, whose parent company is FMC, proposes to add six dialysis stations to its existing facility for a total of 26 certified dialysis stations upon completion of this proposed project.

According to the January 2015 SDR, there are four dialysis facilities in Gaston County and all are ultimately operated and controlled by FMC, as follows:

Name of Facility	Owner	Location	Number of Stations	Utilization
BMA Kings Mountain	BMA	Kings Mountain	14	75.00%
FMC Belmont	FMC	Belmont	16	81.25%
FMC Gastonia	FMC	Gastonia	39	83.33%
FMC South Gaston	FMC	Gastonia	20	91.25%

As shown in the Gaston County Dialysis Facility Data table above, FMC South Gaston was operating at over 91% of capacity as of June 30, 2014. FMC Belmont and FMC Gastonia were operating at 81.25% and 83.33%, respectively, and BMA Kings Mountain was operating at 75% of capacity. In Section III.9, page 36, the applicant explains why it did not propose to relocate existing stations from the BMA Kings Mountain facility, which has a utilization rate below 80.0%, to satisfy the facility need at FMC South Gaston. It states that as of December 31, 2014 “*all of the BMA facilities were utilized at rates exceeding 80%.*”

According to Table B in the January 2015 SDR, there is a need for three dialysis stations in Gaston County. However, the applicant is applying for additional stations based on the facility need methodology. In Section III.7, page 33, the applicant demonstrates that FMC South Gaston will serve a total of 87 in-center patients on 26 dialysis stations at the end of the first operating year, which is 3.35 patients per station per week, or a utilization rate of 83.66% ( $87/26 = 3.35$ ;  $3.35/4 = 83.66\%$ ). Therefore, the facility is expected to serve more than 3.2 patients per station per week at the end of the first operating year as required by 10A NCAC 14C .2203(b).

The applicant adequately demonstrates the proposed project would not result in the unnecessary duplication of existing or approved dialysis services 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.

C

In Section VII.1, page 50, the applicant states that FMC South Gaston currently employs 15.95 full time equivalent (FTE) positions and that it proposes to add two additional FTEs upon project completion for a total of 17.95 FTE positions, as illustrated in the table below:

<b>FMC South Gaston Full-Time Equivalent (FTE) Positions</b>			
Position	Current	Additional	Total
RN	3.00		3.00
Technician	9.00	2.00	11.00
Clinical Manager	1.00		1.00
FMC Director of Operations	0.20		0.20
Dietitian	0.50		0.50
Social Worker	0.50		0.50
Chief Technician	0.10		0.10
Equipment Technician	0.50		0.50
In-Service	0.15		0.15
Clerical	1.00		1.00
<b>Total FTEs</b>	<b>15.95</b>	<b>2.00</b>	<b>17.95</b>

In Section V.4(c), page 42, the applicant states that Dr. Chiefetz will serve as Medical Director for the facility. In Exhibit 21, the applicant provides a letter from Dr. Paul Chiefetz, dated March 2, 2015, indicating his willingness to continue to serve as Medical Director of the facility. In Section VII.4, page 51, the applicant states it does not anticipate any difficulties in filling staff positions. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section V.1, page 40, the applicant lists the providers of the necessary ancillary and support services. See Exhibits 15, 25 and 26 for service agreements documentation. The applicant discusses coordination with the existing health care system on page 43, stating that it has been providing dialysis services at FMC South Gaston over several years and that during that time it has forged relationships with physicians, hospitals, and other health care professionals in the community and *“enjoys the support of the medical community and community leadership.”* The applicant adequately demonstrates the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing healthcare 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 VI.1, page 45, the applicant states:

“BMA has a long history of providing dialysis services to the underserved populations of North Carolina. ... The patient population of the FMC South Gaston facility is comprised of the following:

<i>Facility</i>	<i>Medicaid/ Low Income</i>	<i>Elderly (65+)</i>	<i>Medicare</i>	<i>Women</i>	<i>Racial Minorities</i>
<i>FMC South Gaston</i>	60.3%	38.2%	88.2%	42.7%	61.8%

*The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 88.2% of the facility treatment reimbursement is from Medicare.”*

In Section, VI.1, page 46, the applicant provides the historical in-center payor mix for FMC South Gaston, as follows:

**Historical Payor Source**

<b>Payor Source</b>	<b>Percentage</b>
Private Pay	0.00%
Commercial Insurance	5.59%
Medicare	73.70%
Medicaid	3.80%
Medicare/Commercial	11.73%
VA	1.12%
Other: Self/Indigent	4.06%
<b>Total</b>	<b>100.00%</b>

The Division of Medical Assistance (DMA) maintains a website which provides the number of persons eligible for Medicaid in North Carolina, and estimates the percentage of uninsured people for each county. The following table illustrates those percentages for Gaston County and statewide.

	<b>2010 Total # of Medicaid Eligibles as % of Total Population *</b>	<b>2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *</b>	<b>2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *</b>
Gaston County	19.8%	8.6%	19.0%
Statewide	16.5%	6.7%	19.7%

\*More current data, particularly with regard to the estimated uninsured percentages, was not available.

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by dialysis facilities. In fact, in 2013 only 6.6% of all newly-diagnosed ESRD patients in North Carolina were under the age of 35, according to the ESRD Network 6 2013 Annual Report. (*ESRD Network 6 2013*

*Annual Report/Data Table 1: ESRD Incidence – One Year Statistics as of 1/1/2013 – 12/31/2013, page 99).*<sup>1</sup>

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina, as well as data sorted by age, race or gender. However, a direct comparison to the applicant's current payor mix would be of little value. The population data by age, race or gender do not include information on the number of elderly, handicapped, minorities or women utilizing health services.

Additionally, The United States Renal Data System, in its *2013 USRDS Annual Data Report*, pages 216-223, provides national statistics for FY 2011:

*“The December 31, 2011 prevalent population included 430,273 patients on dialysis ....”*<sup>2</sup> (p. 216)

The report also provides the incidence of dialysis patients in 2011, adjusted by age, gender and race, which show that 65.4% were white, 28.0% were African American, 15.0% were Hispanic, 4.7% were Asian, and 1.2% were Native American (p.218). Moreover, the prevalence of ESRD for the 65-74 year old population grew by 31% since 2000 and by 48% for those aged 75 and older (p. 223). The report further states:

*“In the 2011 prevalent population, 84 percent of hemodialysis patients and 81 percent of those on peritoneal dialysis had some type of primary Medicare coverage, compared to just 53 percent of those with a transplant.”* (p. 216).

The Southeastern Kidney Council (SKC) Network 6 2013 Annual Report provides prevalence data on North Carolina ESRD patients by age, race and gender on page 101, summarized as follows:

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<sup>1</sup><http://www.esrdnetwork6.org/utills/pdf/annual-report/2013%20Network%206%20Annual%20Report.pdf>

<sup>2</sup> [www.usrds.org/adr.aspx](http://www.usrds.org/adr.aspx)

<b>Number and Percent of Dialysis Patients by Age, Race, and Gender 2013</b>		
	<b># of ESRD Patients</b>	<b>% of Dialysis Population</b>
<b>Age</b>		
0-19	65	0.4%
20-34	766	5.0%
35-44	1,498	9.7%
45-54	2,746	17.8%
55-64	4,039	26.2%
65+	6,275	40.8%
<b>Gender</b>		
Female	6,845	44.5%
Male	8,544	55.5%
<b>Race</b>		
African-American	9,559	62.1%
White/Caucasian	5,447	35.4%
Other	383	2.5%

Source: SKC Network 6. Table includes North Carolina statistics only.<sup>3</sup>

The 2013 *USRDS Annual Data Report* provides 2011 ESRD spending by payor, as follows:

<b>ESRD Spending by Payor*</b>		
<b>Payor</b>	<b>Spending in Billions</b>	<b>% of Total Spending</b>
Medicare Paid	\$30.7	62.4%
Medicare Patient Obligation	\$4.7	9.6%
Medicare HMO	\$3.6	7.3%
Non-Medicare	\$10.2	20.7%
<b>Total</b>	<b>\$49.2</b>	<b>100.0%</b>

\*Source: 2013 USRDS Annual Data Report, page 332.

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;

C

<sup>3</sup><http://www.esrdnetwork6.org/utills/pdf/annual-report/2013%20Network%206%20Annual%20Report.pdf>

In Section VI.1, page 47, the applicant states,

*“BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations. The facility will be responsible to provide care to both minorities and handicapped people. ...In accepting payments from Medicare, Title XVIII of the Social Security Act, and Medicaid, Title XIX, all BMA North Carolina Facilities are obligated to meet federal requirements of the Civil Rights Act, Title VI and the Americans with Disabilities Act.”*

In Section VI.6, page 48, 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 VI.1(c), page 46, the applicant provides the projected payor mix for the proposed services at FMC South Gaston as shown in the table below:

<b>Payor Source</b>	<b>Percentage</b>
Private Pay	0.00%
Commercial Insurance	5.59%
Medicare	73.70%
Medicaid	3.80%
Medicare/Commercial	11.73%
VA	1.12%
Other: Self/Indigent	4.06%
<b>Total</b>	<b>100.00%</b>

As shown in the table above, the applicant projects that 89.2% of in-center patients will have some or all of their services paid for by Medicare or Medicaid. The applicant demonstrates that medically underserved populations would 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 VI.5, page 48, 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 South Gaston will have an open policy, which means that any Nephrologist may apply to admit patients at the facility. The attending physicians receive referrals from other physicians or Nephrologists or hospital emergency rooms.”*

The applicant adequately demonstrates that FMC South Gaston will provide a range of means by which a person can access its 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 V.3, page 41, the applicant states that Exhibit 19 includes a letter from the applicant encouraging Gaston College’s nursing program to include FMC South Gaston as a training site for nursing students. The letter in Exhibit 19, dated March 15, 2015, invites the college to include the facility as a site for clinical rotations for nursing students and to expose them to *“other nursing career tracks within the nursing profession.”* The information provided in Section V.3 and Exhibit 19 is reasonable 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

Bio-Medical Applications of North Carolina, Inc., d/b/a FMC South Gaston, whose parent company is Fresenius Medical Care Holdings Inc., (FMC), proposes to add six dialysis

stations to its existing facility for a total of 26 certified dialysis stations upon completion of the proposed project.

The January 2015 SDR shows there is a deficit of three dialysis stations in Gaston County. In this proposal the applicant is applying for additional stations based on the facility need methodology. According to the January 2015 SDR there are four ESRD facilities (including FMC South Gaston) which are currently operational in Gaston County. All of these dialysis facilities are ultimately owned and operated by FMC and are listed as follows:

Name of Facility	Owner	Location	Number of Stations	Utilization
BMA Kings Mountain	BMA	Kings Mountain	14	75.00%
FMC Belmont	FMC	Belmont	16	81.25%
FMC Gastonia	FMC	Gastonia	39	83.33%
FMC South Gaston	FMC	Gastonia	20	91.25%

As of June 30, 2014, FMC South Gaston was operating at 91.25% capacity with 20 dialysis stations (73 patients /20 stations = 3.65/4 = 0.9125 or 91.25%). The target utilization is 80% or 3.2 patients per station per week as of the end of the first operating year of the facility.

In Section V.7, page 44, the applicant discusses how any enhanced competition in the service area will have a positive impact on 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. According to the January 2015 SDR there are four dialysis facilities operating within Gaston County. These facilities offer 89 dialysis stations to the ESRD patients of Gaston County. BMA seeks the opportunity to continue providing dialysis care and treatment to the patients of the area who choose dialysis at a BMA facility.*

*This facility also has added value stemming from the strength of our relationship with Metrolina Nephrology Associates. ...the practice brings together the collaborative efforts of 31 very qualified nephrologists to provide care for the patients choosing to dialyze at FMC South Gaston.*

*BMA facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid. ... In this application, BMA projects that greater than 84% of the In-center patients will be relying upon either Medicare or Medicaid. The facility must capitalize upon every opportunity for efficiency.*

*BMA facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients. ...*

*This proposal will ... enhance the quality of the ESRD patients' lives."*

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicant in those sections is reasonable and adequately demonstrates that any enhanced competition in the service area will have a positive impact on cost-effectiveness, quality and access to the proposed dialysis 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 a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criterion (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates it will continue to provide quality services. The discussion regarding quality found in Criterion (1) and (20), is incorporated herein by reference.
- The applicant demonstrates it will continue to provide adequate access to medically underserved populations. The discussion regarding access found in Criteria (1) and (13) is 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.

FMC Gaston is an existing facility. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, FMC South Gaston has operated in compliance with all Medicare Conditions of Participation within the eighteen months immediately preceding the date of this decision. Therefore, 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 proposal is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services in 10A NCAC 14C .2200. The specific findings are discussed below.

**10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT**

*(a) An applicant that proposes to increase dialysis stations in an existing certified facility or relocate stations must provide the following information:*

(1) *Utilization rates;*

-C- In Section II.1, page 12, the applicant states the utilization rate was 91.25% or 3.65 patients per station ( $73/20 = 3.65$ ) as reported in the January 2015 SDR.

(2) *Mortality rates;*

-C- In Section II.1, page 11, the applicant states the mortality rates were 21.3%, 6.5% and 11.7% for 2012, 2013 and 2014, respectively.

(3) *The number of patients that are home trained and the number of patients on home dialysis;*

-NA- In Section II.1, page 10, the applicant states that FMC South Gaston is not certified to provide home dialysis.

(4) *The number of transplants performed or referred;*

-C- In Section II.1, page 10, the applicant states that FMC South Gaston referred four transplants in 2013 and two were performed. In 2014, 10 transplants were referred and one was performed.

(5) *The number of patients currently on the transplant waiting list;*

-C- In Section II.1, page 10, the applicant states that FMC South Gaston currently has three patients on the transplant waiting list.

(6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*

-C- In Section II.1, page 11, the applicant states that there were 101 hospital admissions in 2014; 13 dialysis related and 88 non-dialysis related.

(7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during last calendar year.*

-C- In Section II.1, page 11, the applicant states that there were no patients at the facility in 2012 or 2013 with an infectious disease.

*(b) An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:*

*(1) For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100.*

-NA- FMC South Gaston is an existing facility.

*(2) For new facilities, a letter of intent to sign a written agreement or a written agreement with transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*

- (A) timeframe for initial assessment and evaluation of patients for transplantation,*
- (B) composition of the assessment/evaluation team at the transplant center,*
- (C) method for periodic re-evaluation,*
- (D) criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and*
- (E) signatures of the duly authorized persons representing the facilities and the agency providing the services.*

-NA- FMC South Gaston is an existing facility.

*(3) For new or replacement facilities, documentation that power and water will be available at the proposed site.*

-NA- FMC South Gaston is an existing facility.

*(4) Copies of written policies and procedures for back up for electrical service in the event of a power outage.*

-C- See Exhibit 12 for a copy of the Emergency Management & Disaster Planning Section of BMA's Policy and Procedure Manual Volume II which includes a policy and procedure for back-up electrical service in the event of a power outage.

(5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*

-NA- FMC South Gaston is an existing facility.

(6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*

-C- In Section II.1, page 12, the applicant states, "*BMA will provide all services approved by the Certificate of Need in conformity with applicable laws and regulations. BMA staffing consistently meets CMS and State guidelines for dialysis staffing. Fire safety equipment, the physical environment, water supply and other relevant health and safety equipment will be appropriately installed and maintained at FMC South Gaston.*"

(7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*

-C- In Section II.1, on page 14, the applicant provides the projected patient origin for FMC South Gaston. All assumptions, including methodology for the projections, are provided in Section III.7, pages 32-34.

(8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*

-NA- FMC South Gaston is an existing facility.

(9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.*

- C- In Section II.1, page 15, the applicant states, “*BMA will admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.*”

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

*(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 South Gaston does not propose to establish a new facility. FMC South Gaston is an existing facility.

*(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 II.1, pages 12-14, the applicant demonstrates the need for six additional dialysis stations for a total of 26 stations, projecting 87 in-center patients at the end of the first operating year for a utilization rate of 3.35 patients per station per week.

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

-C- The applicant provides all assumptions, including the methodology by which patient utilization is projected, in Section II.1, pages 12-14, and Section III.7, pages 31-34.

#### **10A NCAC 14C .2204 SCOPE OF SERVICES**

*To be approved, the applicant must demonstrate that the following services will be available:*

*(1) diagnostic and evaluation services;*

-C- In Section II.1, page 17, the applicant states, “*Patients will be referred to Caromont Regional Hospital.*”

*(2) maintenance dialysis;*

- C- In Section II.1, page 17, the applicant states that FMC South Gaston will provide in-center maintenance dialysis.
- (3) *accessible self-care training;*
- C- In Section II.1, page 17, the applicant states, “*Patients who are candidates for self-care will be referred to the BMA Gastonia home training department.*”
- (4) *accessible follow-up program for support of patients dialyzing at home;*
- C- In Section II.1, page 17, the applicant states, “*Patients who are candidates for home dialysis will be referred to the BMA Gastonia home training department.*”
- (5) *x-ray services;*
- C- In Section II.1, page 17, the applicant states, “*Patients will be referred to Caromont Regional Hospital.*”
- (6) *laboratory services;*
- C- In Section II.1, page 17, the applicant states, “*BMA provides on site laboratory services through contract with Spectra Labs.*” See Exhibit 15 for the laboratory services agreement with Spectra Laboratories.
- (7) *blood bank services;*
- C- In Section II.1, page 17, the applicant states, “*Patients will be referred to Caromont Regional Hospital.*”
- (8) *emergency care;*
- C- In Section II.1, page 17, the applicant states, “*Emergency care for patients is provided on site by BMA staff until emergency responders arrive. In the event of an adverse event while in the facility, BMA staff are appropriately trained; in addition a fully stocked ‘crash cart’ is maintained at the facility. If the patient event requires transportation to a hospital, emergency services are summoned via phone call to 911.*”
- (9) *acute dialysis in an acute care setting;*
- C- In Section II.1, page 17, the applicant states, “*Patients will be referred to Caromont Regional Hospital.*”
- (10) *vascular surgery for dialysis treatment patients;*

-C- In Section II.1, page 18, the applicant states, “*Patients will be referred to Caromont Heart and Vascular, Gastonia Surgical Associates, Surgical Specialists (of Gastonia), or Metrolina Nephrology Associates Access Center. The surgeons of these locations will coordinate with the patient and schedule vascular surgery.*”

(11) *transplantation services;*

-C- In Section II.1, page 18, the applicant states, “*FMC South Gaston has a transplant agreement with CMC.*” See Exhibit 26 for a copy of the transplant agreement.

(12) *vocational rehabilitation counseling and services; and*

-C- In Section II.1, page 18, the applicant states, “*Patients in need of vocational rehabilitation services will be referred to the Division of Vocational Rehabilitation of Gaston County.*”

(13) *transportation.*

-C- In Section II.1, page 18, the applicant states, “*Transportation services are provided by Access of Gaston County.*”

#### **10A NCAC 14C .2205 STAFFING AND STAFF TRAINING**

*(a) To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R., Section 405.2100.*

-C- In Section VII.2, page 51, BMA states that all staffing requirements are and will be met as stated in 42 C.F.R. Section 494 (formerly 405.2100). In Section VII.1, page 50, the applicant provides a proposed staffing chart, and on page 53, provides a table showing the number of direct care staff for each shift to be offered at the facility. The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

*(b) To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.*

-C- In Section II.1, page 18, and Section VII.5, page 51, the applicant describes the training required for all BMA employees. Exhibit 9 contains an outline of the training program and Exhibit 10 contains an outline of continuing education programs and requirements.