

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: November 18, 2016

Findings Date: November 18, 2016

Project Analyst: Gregory F. Yakaboski

Team Leader: Lisa Pittman

Project ID #: F-11229-16

Facility: FMC South Gaston

FID #: 070531

County: Gaston

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

Project: Add 2 dialysis stations for a total of 28 dialysis stations upon completion of this project and Project ID #F-11008-15 (add 6 dialysis stations)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a FMC South Gaston (“the applicant”) proposes to add two dialysis stations for a total of 28 certified dialysis stations at the FMC South Gaston facility upon completion of this project and Project ID #F-11008-15 (add 6 dialysis stations)

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 July 2016 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of four dialysis stations 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 South Gaston in the July 2016 SDR is 3.85 patients per station per week, or 96.25% (3.85 / 4 patients per station = 0.9625 or 96.25%). This utilization rate was calculated based on 77 in-center dialysis patients and 20 certified dialysis stations (77 patients / 20 stations = 3.85 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:

OCTOBER 1 REVIEW-JULY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/15		96.3%
Certified Stations		20
Pending Stations		6
Total Existing and Pending Stations		26
In-Center Patients as of 12/31/15 (July 2016 SDR) (SDR2)		77
In-Center Patients as of 6/30/15 (Jan 2016 SDR) (SDR1)		71
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	6
	Multiply the difference by 2 for the projected net in-center change	12
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/15	0.1690
(ii)	Divide the result of Step (i) by 12	0.0141
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/14 until 12/31/15)	0.1690
(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	90.0141
(v)	Divide the result of Step (iv) by 3.2 patients per station	28.1294
	and subtract the number of certified and pending stations to determine the number of stations needed	2.1294

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is two stations. Step (C) of the facility need methodology states, “*The facility may apply to expand to meet the need established ..., up to a maximum of ten stations.*” The applicant proposes to add two new stations, therefore the application is consistent with the facility need determination for dialysis stations.

Policies

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

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

Promote Safety and Quality

The applicant describes how it believes the proposed project would promote safety and quality in Section B, pages 12, 14-15, Section O, pages 58-64 and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project would promote equitable access in Section B, page 13, 14-15, Section C, page 19, Section I, pages 41-44, Section L, pages 51-55 and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project would maximize healthcare value in Section B, pages 13-15, Section N, page 57, and referenced exhibits. The information

provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would maximize healthcare value.

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

Conclusion

In summary, the applicant adequately demonstrates that the proposal is consistent with the facility need methodology in the July 2016 SDR and Policy Gen-3. Therefore, the application is conforming to this criterion.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

BMA proposes to add two dialysis stations for a total of 28 certified dialysis stations at the FMC South Gaston facility upon completion of this project and Project ID #F-11008-15 (add 6 dialysis stations)

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

Patient Origin

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

In Section C, page 21, the applicant provides a table showing the historical patient origin for in-center (IC) patients served by FMC South Gaston, as shown below:

Dialysis Patients as of 6/30/2016

COUNTY	IC PATIENTS
Gaston	70
South Carolina	6
Total	76

In Section C, page 17, the applicant identifies the patient population it proposes to serve during the first two years of operation following project completion, as illustrated in the table below:

Projected Patient Origin OY1 and OY2

COUNTY	IC PATIENTS OY1 (CY2018)	IC Patients OY2 (CY2019)
Gaston	84.9	91.7
South Carolina	6.0	6.0
Total	90.9	97.7

The applicant provides the assumptions and methodology for the projections above on pages 17-19.

The applicant adequately identifies the population it proposes to serve.

Analysis of Need

In Section B-2, pages 9-10, the applicant states the need for the proposed project is based on the facility need methodology. The discussion regarding the need determination found in Criterion (1) is incorporated herein by reference.

Projected Utilization

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

COUNTY	OPERATING YEAR 1 CY2018			OPERATING YEAR 2 CY2019			COUNTY PATIENTS AS % OF TOTAL	
	IC	HH	PD	IC	HH	PD	OY 1	OY 2
Gaston	84.9	na	na	91.7	na	na	93.4%	93.9%
South Carolina	6.0	na	na	6.0	na	na	6.6%	6.1%
Total	90.9	na	na	97.7	na	na	100.0%	100.0%

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

FMC South Gaston
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Page 6

- Operating Year 1 (CY2018) = January 1 – December 31, 2018
- Operating Year 2 (CY2019)= January 1 – December 31, 2019
- BMA assumes that the patients dialyzing at FMC South Gaston who are residents of Gaston County and South Carolina are at FMC South Gaston by choice and will continue to dialyze at FMC South Gaston.
- BMA indicates that the Five Year Average Annual Growth Rate for Gaston County (6.9%) is not an appropriate growth factor for projecting future patient populations of the FMC South Gaston facility.
- A growth rate of 8.0% was used for the facility patient population from Gaston County which represents slightly less than half of the 16.9% annual growth rate for the facility based on the Facility Need Methodology calculation.
- BMA does not project any increase of the patients who reside in South Carolina but does add these patients into its projections.

Begin with the facility census of patients who reside in Gaston County on June 30, 2016.	70
Project the census forward for six months to December 31, 2016 using one half of the 8.0% growth rate.	$1.04 \times 70 = 72.8$
Project this patient population forward one year to December 31, 2017 using the 8.0% growth rate.	$1.08 \times 72.8 = 78.624$
Project this Gaston County patient population forward one year to December 31, 2018.	$1.08 \times 78.624 = 84.9$
Add the 6 patients who reside in South Carolina. This is the projected ending census for Operating Year 1 (CY2018)	$84.9 + 6 = 90.9$
Project the Gaston County patient population forward one year to December 31, 2019.	$1.08 \times 84.9 = 91.7$
Add the 6 patients who reside in South Carolina. This is the projected ending census for Operating Year 2 (CY2019).	$91.7 + 6 = 97.7$

Projected patients for OY1 and OY2 are rounded down to the nearest whole number. Therefore, at the end of OY1 (CY 2018) the facility is projected to serve 90 in-center patients and at the end of OY2 (CY2019) the facility is projected to serve 97 in-center patients.

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

- OY1: 3.214 patients per station per week, or 80.35% ($90 \text{ patients} / 28 \text{ stations} = 3.214/4 = 0.8035$ or 80.35%).

- OY2: 3.46 patients per station per week, or 86.6% (97 patients / 28 stations = 3.464/4 = 0.866 or 86.6%).

The projected utilization of 3.214 patients per station per week at the end of OY1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

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

Access

In Section L, pages 51-52, the applicant states that each of BMA’s 105 facilities in 42 North Carolina counties has a patient population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, and other underserved persons. The table below shows the historical payment sources of the facility for CY2015 including that 89.59% of its patients were Medicare or Medicaid recipients

Payment Source	Percent of Total Patients
Private Pay	2.36%
Commercial Insurance	7.88%
Medicare	77.47%
Medicaid	3.94%
Miscellaneous (Incl. VA)	0.17%
Other: Medicare/Commercial Insurance	8.18%

The applicant projects 88.09% of its patients will be Medicare or Medicaid recipients in CY2019. The applicant adequately demonstrates the extent to which all residents of the service area, including underserved groups, are likely to have access to its services.

Conclusion

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

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial

and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

In Section E-1, page 25, the applicant discusses the alternatives considered prior to submitting this application, which include:

1. Maintain the Status Quo - the applicant states that this option would result in higher utilization rates and potentially impact patient access to care.
2. Relocate stations from other BMA facilities within Gaston County- The applicant states that all of the other BMA facilities within Gaston County are currently operating above 80% utilization.
3. Add home therapies- The physical plant does not have the requisite space to add home therapies.

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

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 South Gaston shall materially comply with all representations made in its certificate of need application.**
- 2. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC South Gaston shall develop and operate no more than 2 additional stations for a total of 28 certified stations which shall include any home hemodialysis training or isolation stations upon completion of this project and Project ID #F-11008-15 (add 6 dialysis 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 the 2 additional dialysis stations for a total of 28 dialysis stations, which shall include any home hemodialysis training or isolation stations, upon completion of this project and Project ID #F-11008-15 (add 6 dialysis 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 Healthcare Planning and Certificate of Need Section in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

BMA proposes to add two dialysis stations for a total of 28 certified dialysis stations at the FMC South Gaston facility upon completion of this project and Project ID #F-11008-15 (add 6 dialysis stations)

Capital and Working Capital Costs

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

Projected Capital Costs	
(RO) water treatment equipment	\$1,500
Equipment/furniture not included above	\$7,900
Total	\$9,400

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

Availability of Funds

In Section F, pages 28-29, the applicant states that accumulated reserves/owners equity will be used to finance the proposed project. In Exhibit F-1 the applicant provides a letter dated September 15, 2016, from Mark Fawcett, Senior Vice President & Treasurer, Fresenius Medical Care Holdings, Inc., which is the parent of 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 \$9,400 for the proposed project.

Exhibit F-2 contains a copy of Fresenius Medical Care Holdings, Inc. and Subsidiaries (FMC) Consolidated Financial Statements for December 31, 2015. As of December 31, 2015, FMC had \$249,300,000 in cash and cash equivalents, \$19,332,539,000 in total assets and \$10,144,288,000 in net assets (total assets less total liabilities). (See Exhibit F-2, page 3)

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

Financial Feasibility

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

FMC SOUTH GASTON		
REVENUE AND EXPENSES - TOTAL FACILITY		
	OPERATING YR 1 CY 2018	OPERATING YR 2 CY 2019
Gross Patient Revenue	\$51,417,284	\$55,552,840
Deductions from Gross Patient Revenue	(\$46,557,646)	(\$50,302,336)
Net Patient Revenue	\$4,859,638	\$5,250,504
Operating Expenses	(\$3,799,283)	(\$4,045,576)
Net Income	\$1,060,354	\$1,204,929

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.

In Section H, page 37, the applicant provides projected staffing and salaries. Form A in Section R, page 1, shows budgeted operating costs adequate to cover the projected staffing. The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

Conclusion

In summary, the applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project. Furthermore, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

BMA proposes to add two dialysis stations for a total of 28 certified dialysis stations at the FMC South Gaston facility upon completion of this project and Project ID #F-11008-15 (add 6 dialysis stations)

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

The July 2016 SDR indicates there are four dialysis facilities in Gaston County, as follows:

**Gaston County Dialysis Facilities
December 31, 2015**

Dialysis Facilities	Owner	# of Patients	Location	# of Certified Stations	# of Approved Stations	Percent Utilization
BMA Kings Mountain	BMA	53	Kings Mountain	16	0	82.81%
FMC Belmont	BMA	67	Belmont	18	0	93.06%
FMC Gastonia	BMA	140	Gastonia	39	0	89.74%
FMC South Gaston	BMA	77	Gastonia	20	6	96.25%

*Source- July 2016 SDR

As illustrated above, all four of the existing facilities are owned and operated by the applicant. There are no other providers of dialysis service in Gaston County. All four of the existing BMA facilities have a utilization rate over 82.0%. Therefore, all of the operational dialysis facilities in the county are well utilized.

In Section C, pages 17-21, the applicant demonstrates that FMC Gaston will serve a total of 90 in-center patients at the end of Operating Year One (CY2018) for a utilization rate of 80.35% or 3.21 patients per station per week ($90 \text{ patients} / 28 \text{ stations} = 3.214 / 4 = .8035$ or 80.35%). The projected utilization of 3.214 patients per station per week for Operating Year One satisfies the 3.2 in-center patients per station per week threshold as required by 10A NCAC 14C .2203(b).

The applicant adequately demonstrates that projected utilization is based on growth of in-center patients at the facility.

The applicant adequately demonstrates the need to add two additional station at FMC South Gaston 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 of 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 37, the applicant provides the following table to illustrate current and projected staffing in full time equivalents (FTEs) for FMC South Gaston. The applicant states the Medical Director is not employed by the facility, and thus is not reflected on the staffing chart.

POSITION	CURRENT # FTES	# FTES TO BE ADDED	PROJECTED # FTES
Registered Nurse	4.00		4.00
Technician (PCT))	8.00	1.00	9.00
Clinical Manager	1.00		1.00
Director of Operations	0.25		0.25
Dietician	0.75		0.75
Social Worker	0.75		0.75
Chief Tech	0.15		0.15
Equipment Tech	0.67		0.67
In-Service	0.20		0.20
Clerical	1.00		1.00
Total	16.77	1.0	16.77

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

In Section H, page 40, the applicant provides the projected direct care staff for FMC South Gaston in Operating Year 2, as shown below in the table:

DIRECT CARE POSITIONS	# FTES	HOURS PER YEAR PER FTE	TOTAL ANNUAL FTE HOURS	TOTAL ANNUAL HOURS OF OPERATION	# FTE HOURS PER HOUR OF OPERATION
Registered Nurse	4.0	2,080	8,320	3,432	2.42
Technician (PCT)	9.0	2,080	18,720	3,432	5.45
Total	13	2,080	27,040	3,432	7.88

In Section I, page 42, the applicant identifies Dr. Paul Cheifetz as the Medical Director of the facility. In Exhibit I-5, the applicant provides a copy of a letter signed by Dr. Cheifetz of Metrolina Nephrology Associates, PA supporting the project and confirming his commitment to serve as Medical Director. In Section H, pages 38, the applicant describes the methods used to recruit and fill vacant or new positions.

The applicant documents the availability of adequate health manpower and management personnel, including the Medical Director, for the provision of the proposed dialysis services. Therefore, the application is conforming to this criterion.

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

C

In Section I, page 42, the applicant includes a list of providers of the necessary ancillary and support services. Exhibit I-5 contains a letter from the medical director of the facility expressing his support for the proposed project. The applicant discusses coordination with the existing health care system on pages 42-44. Exhibits I-1 through I-4, respectively, contain copies of agreements for home training, lab services, acute services and transplantation. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates:

- (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and
- (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
 - (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
 - (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L, page 55, the applicant reports that 89.59% of the patients who received treatments at FMC South Gaston had some or all of their services paid for by Medicare or Medicaid in the past year. The table below shows the historical payment sources of the facility in CY2015:

Payment Source	Percent of Total Patients
Private Pay	2.36%
Commercial Insurance	7.88%
Medicare	77.47%
Medicaid	3.94%
Miscellaneous (Incl. VA)	0.17%
Other: Medicare/Commercial Insurance	8.18%

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.

Percent of Population						
County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
Gaston	15%	52%	25%	17%	13%	18%
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:

Number and Percent of Dialysis Patients by Age, Race, and Gender 2014		
	# of ESRD Patients	% of Dialysis Population
Age		
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%
Gender		
Female	7,064	44.2%
Male	8,934	55.8%
Race		
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 53). In Section L, page 54, 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 51, 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 52, the applicant projects that 88.09% of all patients in CY2019 who will receive dialysis treatments at FMC South Gaston will have all or part of their services paid for by Medicare and or Medicaid, as indicated in the table below:

Payment Source	Percent of Total Patients
Private Pay	2.04%
Commercial Insurance	9.40%
Medicare	76.95%
Medicaid	4.11%
Miscellaneous (Incl. VA)	0.47%
Other: Medicare/Commercial Insurance	7.03%
Total	100.00%

The projected payor mix reflects the historical payor mix. The applicant demonstrates that medically underserved populations will have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section L, page 54, 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 has an open policy, which means that any Nephrologist may apply to admit patients to the facility. The attending physicians receive referrals from other physicians or Nephrologists or hospital emergency rooms. ... Transient patients are accepted upon proper coordination of care with the patient’s regular nephrologist and a physician with staff privileges at the facility.”

The applicant adequately demonstrates that FMC South Gaston 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 56 the applicant states that FMC South Gaston 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 South Gaston and Gaston College however, Exhibit M-1 does contain a letter from BMA to Gaston College offering the FMC South Gaston facility to be included in Gaston College’s list of facilities for clinical rotation of its nursing students. The information provided in Section M is reasonable and credible and supports a finding of conformity to this criterion.

- (15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

BMA proposes to add two dialysis stations for a total of 28 certified dialysis stations at the FMC South Gaston facility upon completion of this project and Project ID #F-11008-15 (add 6 dialysis stations)

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

The July 2016 SDR indicates there are four dialysis facilities in Gaston County, as follows:

**Gaston County Dialysis Facilities
December 31, 2015**

Dialysis Facilities	Owner	# of Patients	Location	# of Certified Stations	# of Approved Stations	Percent Utilization
BMA Kings Mountain	BMA	53	Kings Mountain	16	0	82.81%
FMC Belmont	BMA	67	Belmont	18	0	93.06%
FMC Gastonia	BMA	140	Gastonia	39	0	89.74%
FMC South Gaston	BMA	77	Gastonia	20	6	96.25%

As illustrated above, all four of the existing facilities are owned and operated by the applicant. There are no other providers of dialysis service in Gaston County. All four of the existing BMA facilities have a utilization rate over 82.0%. Therefore, all of the operational dialysis facilities in the county are well utilized.

In Section C, pages 17-21, the applicant demonstrates that FMC Gaston will serve a total of 90 in-center patients at the end of Operating Year One (CY2018) for a utilization rate of 80.35% or 3.21 patients per station per week (90 patients / 28 stations = 3.214 / 4 = .8035 or 80.35%). The projected utilization of 3.214 patients per station per week for Operating Year One satisfies the 3.2 in-center patients per station per week threshold as required by 10A NCAC 14C .2203(b).

In Section N, page 57, 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 South Gaston facility begins with

patients currently served by BMA, and a growth of that patient population at a rate of 9.52% [sic]; this is equivalent to recent facility experience.”

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

The information provided by the applicant in the sections referenced above is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on the cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application, and the following analysis:

- The applicant adequately demonstrates the need for the proposed project and that it is an effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates that FMC South Gaston will continue to provide quality dialysis services. The discussion regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- The applicant demonstrates that FMC South Gaston will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (1), (3) and (13) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Section B, pages 12 and 14-15, and Section O, pages 58-60, and Exhibit O-1, the applicant discusses the methods it uses to ensure and maintain quality. On page 60 the applicant states that the FMC South Gaston facility meets the Conditions for Coverage for ESRD facilities. See also Exhibit O-2.

In Section O, page 61, the applicant lists three facilities that were cited for deficiencies that resulted in a finding of Immediate Jeopardy during the 18 month look back period: BMA Lumberton, BMA East Charlotte and RAI West College-Warsaw. See the table below which

shows the survey dates and if the facilities are back in compliance with CMS. See also Exhibits O-3-5.

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

Based on a review of 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 17-21, the applicant demonstrates that FMC South Gaston will serve a total of 90 in-center patients on 28 stations at the end of Operating Year One (CY2018) for a utilization rate of 80.35% or 3.21 patients per station per week (90 patients / 28 stations = 3.214 / 4 = .8035 or 80.35%). The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

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

-C- In Section C, pages 17-21, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.