

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 2, 2017

Findings Date: June 2, 2017

Project Analyst: Gregory F. Yakaboski

Team Leader: Lisa Pittman

Project ID #: F-11309-17

Facility: FMC Gastonia

FID #: 955615

County: Gaston

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

Project: Add six dialysis stations to the existing facility for a total of 33 stations upon completion of this project and Project I.D. #F-11266-16 (relocate 12 dialysis stations from FMC Gastonia to develop the new FKC North Gaston facility).

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Agency 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 and/or the applicant), d/b/a FMC Gastonia (FMC Gastonia and/or the facility) proposes to add six dialysis stations to the existing facility for a total of 33 dialysis stations upon completion of this project and Project ID #F-11266-16 (relocation of 12 dialysis stations from FMC Gastonia to develop the new FKC North Gaston facility). FMC Gastonia offers a home hemodialysis and peritoneal program.

Need Determination

The 2017 State Medical Facilities Plan (2017 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2017 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of three 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 Gastonia in the January 2017 SDR is 3.64 patients per station per week, or 91.03% (3.641 / 4 patients per station = 0.91025 or 91.03%). This utilization rate was calculated based on 142 in-center dialysis patients and 39 certified dialysis stations (142 patients / 39 stations = 3.6410 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:

APRIL 1 REVIEW-JANUARY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/16		91.03%
Certified Stations		39
Pending Stations		0
Total Existing and Pending Stations		39
In-Center Patients as of 6/30/16 (SDR2)		142
In-Center Patients as of 12/31/15 (SDR1)		140
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	2
	Multiply the difference by 2 for the projected net in-center change	4
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/15	0.0286
(ii)	Divide the result of step (i) by 12	0.0024
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/16 until 12/31/16)	0.0143
(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	144.0286
(v)	Divide the result of step (iv) by 3.2 patients per station	45.0089
	and subtract the number of certified and pending stations to determine the number of stations needed	6

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is six 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 six new stations, therefore the application is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2017 SMFP which is applicable to this review. *POLICY GEN-3: BASIC PRINCIPLES* on page 33 of the 2017 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 60-64, 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, pages 13-15, Section C, page 20, Section I, pages 41-44, Section L, pages 52-56, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project would maximize healthcare value in Section B, pages 14-15, Section N, pages 58-59, 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 2017 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 six dialysis stations to the existing facility for a total of 33 dialysis stations upon completion of this project and Project ID #F-11266-16 (relocation of 12 dialysis stations from FMC Gastonia to develop the new FKC North Gaston facility). FMC Gastonia offers a home hemodialysis and peritoneal program.

Patient Origin

On page 373, the 2017 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining North Carolina counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Gaston County. Facilities may also serve residents of counties not included in their service area.

In Section C, page 23, the applicant provides a table showing the historical patient origin for both in-center (IC) patients, home hemodialysis (HH) patients and peritoneal (PD) patients served by FMC Gastonia, as shown below:

COUNTY	IC	HH	PD
Gaston	134	16	8
Cabarrus	1		
Cleveland	1	9	5
Lincoln	1	4	6
Mecklenburg	1	2	
Rutherford			1
Virginia	1		
South Carolina		6	
Totals	139	37	20

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

COUNTY	OPERATING YEAR 1 CY2019			OPERATING YEAR 2 CY2020			COUNTY PATIENTS AS % OF TOTAL	
	IC	HH	PD	IC	HH	PD	OY 1	OY 2
Gaston	138.0	17.4	7.6	147.6	18.6	8.2	81.5%	82.5%
Cabarrus	1.0	0.0	0.0	1.0	0.0	0.0	0.5%	0.5%
Cleveland	1.0	9.0	5.0	1.0	9.0	5.0	7.5%	7.1%
Lincoln	1.0	4.0	6.0	1.0	4.0	6.0	5.5%	5.2%
Mecklenburg	1.0	2.0	0.0	1.0	2.0	0.0	1.5%	1.4%
Rutherford	0.0	0.0	1.0	0.0	0.0	1.0	0.5%	0.5%
South Carolina	0.0	6.0	0.0	0.0	6.0	0.0	3.0%	2.8%
Totals	142	38	19	151	39	20	100.0%	100.0%

The applicant provides the assumptions and methodology for the projections above on pages 17-20. The applicant adequately identifies the population it proposes to serve.

Analysis of Need

In Section B-2, pages 9-10, the applicant states the need for the proposed project is based on the facility need methodology. The discussion regarding the need determination found in Criterion (1) is incorporated herein by reference. See also Section C-2, page 20.

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 CY2019			OPERATING YEAR 2 CY2020			COUNTY PATIENTS AS % OF TOTAL	
	IC	HH	PD	IC	HH	PD	OY 1	OY 2
Gaston	138.0	17.4	7.6	147.6	18.6	8.2	81.5%	82.5%
Cabarrus	1.0	0.0	0.0	1.0	0.0	0.0	0.5%	0.5%
Cleveland	1.0	9.0	5.0	1.0	9.0	5.0	7.5%	7.1%
Lincoln	1.0	4.0	6.0	1.0	4.0	6.0	5.5%	5.2%
Mecklenburg	1.0	2.0	0.0	1.0	2.0	0.0	1.5%	1.4%
Rutherford	0.0	0.0	1.0	0.0	0.0	1.0	0.5%	0.5%
South Carolina	0.0	6.0	0.0	0.0	6.0	0.0	3.0%	2.8%
Totals	142	38	19	151	39	20	100.0%	100.0%

In Section C, pages 17-20, the applicant provides the assumptions and methodology used to project utilization. On page 18, the applicant provides a table illustrating how utilization was projected, which is summarized below:

- Operating Year 1 = Calendar Year 2019 (CY2019)
- Operating Year 2 = Calendar Year 2020 (CY2020)

- In projecting future patients at FMC Gastonia the applicant starts with 139 in-center patients based on the ESRD Data Collection form for the period ending December 31, 2016 which indicates the FMC Gastonia in-center patient census was 139 of which five patients are not residents of Gaston County. Of the five in-center patients who are not residents of Gaston County one was from Virginia. The applicant assumes the Virginia resident was transient and does not include this patient in its projected patient utilization. BMA assumes the remaining four in-center patients who are not residents of Gaston County utilized the FMC Gastonia facility by choice and will continue to dialyze at FMC Gastonia. However, BMA does not project an increase in this segment of the population utilizing FMC Gastonia
- BMA states that to project annual growth of the in-center patients who are residents of Gaston County it applied the Five Year Average Annual Growth Rate (AAGR) for Gaston County (6.9%) published in the January 2017 SDR.
- Effective December 31, 2018, BMA subtracts out the 24 in-center patients from Gaston County who currently utilize the FMC Gastonia facility but are projected to transfer to the FKC Gaston facility upon that facility becoming certified.

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

Begin with the 134 in-center patients from Gaston County utilizing FMC Gastonia as of December 31, 2016.	134
Project this Gaston County patient population forward one year to December 31, 2017 using the 6.9% AAGR	$1.069 \times 134 = 143.246$
Project this Gaston County patient population forward one year to December 31, 2018 using the 6.9% AAGR	$1.069 \times 143.246 = 153.1299$
Subtract out the 24 Gaston County in-center patients projected to transfer to the new FKC Gaston facility. Beginning census for Operating Year 1 (CY2019)	$153.1299 - 24 = 129.1299$
Project this Gaston County patient population forward one year to December 31, 2019 using the 6.9% AAGR	$1.069 \times 129.1299 = 138$
Add 4 in-center patients who reside outside Gaston County. This is the projected ending census for Operating Year 1 (CY2019).	$138 + 4 = 142$
Project this Gaston County patient population forward one year to December 31, 2020 using the 6.9% AAGR	$1.069 \times 138 = 147.5$
Add 4 in-center patients who reside outside Gaston County. This is the projected ending census for Operating Year 2 (CY2020).	$147.5 + 4 = 151.5$

Projected patients for OY1 and OY2 are rounded down to the nearest whole number. Therefore, at the end of OY1 (CY 2019) the facility is projected to serve 142 in-center patients and at the end of OY2 (CY2020) the facility is projected to serve 151 in-center patients.

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

- OY1: 4.3 patients per station per week or 107.5% ($142 \text{ patients} / 33 \text{ stations} = 4.3 / 4 = .1.075$ or 107.5%).

- OY2: 4.575 patients per station per week or 114.37% (151 patients / 33 stations = $4.575/4 = 1.1437$ or 114.37%).

The projected utilization of 4.3 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).

The applicant projects home hemodialysis and home peritoneal dialysis utilizing the same growth rate and methodology. (See application pages 17-19)

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

Access

In Section L, pages 52-53, the applicant states that each of BMA's 108 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 percent of total patients by payment sources or the facility in CY2016 and shows that 82.61% of the patients were Medicare or Medicaid recipients

Payment Source	Percent of Total Patients
Commercial Insurance	15.56%
Medicare	68.93%
Medicaid	4.42%
Medicare/Commercial	9.26%
Miscellaneous (Incl. VA)	1.99%
Total	100.00%

The applicant projects 81.16% of its patients will be Medicare or Medicaid recipients in OY2 (CY2020). 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 26, the applicant discusses the alternatives considered prior to submitting this application, which include:

1. Maintain the Status Quo – the applicant states that additional stations are needed at FMC Gastonia, not developing additional capacity at FMC Gastonia will result in higher utilization rates and potentially restrict patient access.
2. Apply for fewer than six stations at the FMC Gastonia facility- The applicant states that projected utilization is greater than 3.2 patients per station and thus it would be inappropriate to apply for fewer than six stations.
3. Relocate existing stations from other BMA facilities in Gaston County- The applicant states that the other BMA facilities do not have excess stations based on existing utilization.

After considering these alternatives to its proposal, the applicant believes the most effective and least costly alternative is to add six stations to ensure adequate access for the patients of FMC Gastonia.

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 for six more stations at FMC Gastonia. Therefore, the application is conforming to this criterion subject to the following conditions:

- 1. Bio-Medical Applications of North Carolina, Inc., d/b/a FMC Gastonia 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 Gastonia shall develop and operate no more than six additional dialysis stations for a total of 33 certified stations following completion of this project and Project ID #F-11266-16 (relocate 12 dialysis stations), which shall include any home hemodialysis training or isolation stations.**
- 3. Bio-Medical Applications of North Carolina, Inc., d/b/a FMC Gastonia 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 the 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 six stations to the facility for a total of 33 stations upon completion of this project and Project I.D. #F-11266-16 (relocation of 12 dialysis stations from FMC Gastonia to develop the new FKC North Gaston). FMC Gastonia offers a home hemodialysis and peritoneal program.

Capital and Working Capital Costs

In Section F, page 27, the applicant states that there are no projected capital costs associated with the proposed project.

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

Financial Feasibility

In the projected revenue and expense statement (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 GASTONIA REVENUE AND EXPENSES		
	OY 1 CY 2019	OY 2 CY 2020
Total Treatments	20,303	21,637
Gross Revenue	\$114,060,788	\$120,561,228
Deductions from Gross Patient Revenue	(\$102,313,852)	(\$108,163,347)
Net Revenue	\$11,746,936	\$12,397,880
Operating Expenses	(\$7,752,538)	(\$6,819,654)
Net Income	\$3,994,398	\$5,578,227

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

Conclusion

In summary, the applicant adequately demonstrates that sufficient funds will be available for the operating 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 six stations to the facility for a total of 33 stations upon completion of this project and Project I.D. #F-11266-16 (relocation of 12 dialysis stations from FMC Gastonia to develop the new FKC North Gaston). FMC Gastonia offers a home hemodialysis and peritoneal program.

On page 373, the 2017 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.

According to the January 2017 SDR, there are four existing dialysis facilities in Gaston County. All of the four facilities are operational, with one having been approved to relocate to another site. In addition, a fifth dialysis facility, Fresenius Kidney Center North Gaston, has been approved but is not yet developed. The applicant or its parent company owns and operates all of the four existing dialysis facilities and the fifth approved, but undeveloped, dialysis facility, in Gaston County as shown below in the table.

GASTON COUNTY DIALYSIS FACILITIES				
Certified and Approved Stations and Utilization as of June 30, 2016				
Facility	Owner	Location	Number of Existing/ Approved Stations	Utilization as of June 30, 2016
FMC Gastonia	BMA	Gastonia	39	91.03%
FMC South Gaston	BMA	Gastonia	26	95.00%
FMC Belmont	BMA	Belmont	19	87.50%
BMA Kings Mountain	BMA	Kings Mountain	16	85.94%
BMA Kings Mountain*	BMA	Kings Mountain	**18	0.00%
Fresenius Kidney Center North Gaston	BMA	Dallas	12	0.00%

Source: Table A, January 2017 SDR

*Proposed new site consisting of existing stations. **CON issued, not certified.

As shown in the table above, all four of BMA’s operational dialysis facilities are operating at or above 85% utilization. Therefore, the facilities are well utilized.

In Section C-1, pages 17-20, the applicant demonstrates that FMC Gastonia will serve a total of 142 in-center patients at the end of OY1 (CY2019) for a utilization rate of 107.5% or 4.3 patients per station per week (142 patients / 33 stations = 4.303 /4 = 1.075 or 107.5%). The projected utilization of 4.3 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 proposes to add six dialysis stations to the existing facility in Gastonia, in Gaston County. The applicant adequately demonstrates the need to add six additional stations at FMC Gastonia based on the number of in-center patients it proposes to serve. The discussion on projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved dialysis stations 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 H, page 38, the applicant provides the following table to illustrate current and projected staffing in full time equivalents (FTEs) for FMC Gastonia. 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	9.00		9.00
Technician (PCT))	15.00		15.00
Clinical Manager	1.00		1.00
Administrator	0.15		0.15
Dietician	1.50		1.50
Social Worker	1.75		1.75
Home Training Nurse	5.00		5.00
Chief Tech	0.15		0.15
Equipment Tech	1.00		1.00
In-Service	1.00		1.00
Clerical	2.00		2.00
Total	37.55	0.00	37.55

As illustrated in the table above, the applicant projects to add 0.00 FTEs at FMC Gastonia.

In Section H, page 40, the applicant provides the projected direct care staff for FMC Gastonia in OY2 (CY2020), 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	9.0	2,080	18,720	5,616	3.33
Technician (PCT)	15.0	2,080	31,200	5,616	5.56
Total	24.0	2,080	49,920	5,616	8.89

In Section H, page 43, the applicant states dialysis services will be available from 7:00 AM to 5:00 PM, Monday through Saturday and 9:00 PM to 5:00 AM Monday through Saturday, for a total of 18 hours per day/ 108 hours per week.

In Section I, page 43, the applicant identifies Dr. Gene Radford as the Medical Director of the facility. In Exhibit I-5, the applicant provides a copy of a letter signed by Dr. Radford of Metrolina Nephrology Associates, PA supporting the project and confirming his commitment to serve as Medical Director. In Section H, pages 39, the applicant describes the methods used to recruit and fill vacant or new positions.

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

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

C

In Section I, page 41, the applicant identifies the necessary ancillary and support services and indicates how they are or will be made available. 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 45-47. Exhibits I-2 through I-4, respectively, contain copies of agreements for lab services, acute services and transplantation services. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

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

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new

members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

- (i) would be available under a contract of at least 5 years duration;
- (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
- (iii) would cost no more than if the services were provided by the HMO; and
- (iv) would be available in a manner which is administratively feasible to the HMO.

NA

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

NA

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

C

In Section L, page 56, the applicant reports that 82.61% of the patients who received treatments at FMC Gastonia 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 CY2016:

Payment Source	Percent of Total Patients
Commercial Insurance	15.56%
Medicare	68.93%
Medicaid	4.42%
Medicare/Commercial	9.26%
Miscellaneous (Incl. VA)	1.99%
Total	100.00%

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 and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2014 Estimate	2014 Estimate	2014 Estimate	2014 Estimate	2010-2014	2010-2014	2014 Estimate
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 IPRO ESRD Network of the South Atlantic Network 6 provides prevalence data on ESRD Network 6 dialysis patients by age, race, and gender on pages 27-28¹. The ESRD Network 6 service area contract, previously managed by Alliant Healthcare Solutions' Southeastern Kidney Council, was awarded to IPRO in April 2016 and is now called the IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6). IPRO SA Network 6 is still comprised of North Carolina, South Carolina and Georgia. The 2015 Annual Report, submitted in November 2016 by IPRO differs somewhat from the reports submitted in the past by The Southeastern Kidney Council.

The statistics on number and percent of dialysis patients by age, gender and race are now shown only in total for Network 6; the statistics are no longer separately shown for North Carolina in the report. However, a comparison of the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report*² percentages for North Carolina and the total Network shows very little variance; therefore the statistics for the total Network 6 are representative of North Carolina's statistics. One would also assume the 2015 percentages for the total Network 6 should also very closely reflect North Carolina percentages by age, gender and race. The following table shows the North Carolina

¹http://esrd.ipro.org/wp-content/uploads/2016/11/2015_NW-6_Annual-Report_Final-Draft-with-COR-Changes-Submitted-11-29-2016.pdf

²<http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf>

and total Network data for 2014 as provided by the Southeastern Kidney Council, and compared with the IPRO 2015 Network totals.

Number and Percent of Dialysis Patients by Age, Race, and Gender 2014 and 2015						
	2014 Patients and Percentages*				2015 Patients and Percentages**	
	NC Patients	NC Percentage	Total Network 6 Patients	Total Network 6 Percentage	Total Network 6 Patients	Total Network 6 Percentage
Age						
0-19	52	0.3%	137	0.3%	137	0.3%
20-34	770	4.8%	2,173	4.9%	2,142	4.7%
35-44	1,547	9.7%	4,385	9.9%	4,493	9.8%
45-54	2,853	17.8%	8,070	18.3%	8,422	18.3%
55-64	4,175	26.1%	11,706	26.5%	12,024	26.1%
65+	6,601	41.3%	17,716	40.1%	18,817	40.9%
Gender						
Female	7,064	44.2%	19,923	45.1%	20,805	45.2%
Male	8,934	55.8%	24,264	54.9%	25,230	54.8%
Race						
African-American	9,855	61.6%	29,191	66.1%	30,092	65.4%
White	5,778	36.1%	14,222	32.2%	15,049	32.7%
Other	365	2.3%	774	1.8%	894	1.9%

*2014 Calendar Year data from the Southeastern Kidney Council Network 6 2014 annual Report at <http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf>

**2015 Calendar Year data from the IPRO ESRD Network of the South Atlantic at http://esrd.ipro.org/wp-content/uploads/2016/11/2015_NW-6_Annual-Report_Final-Draft-with-COR-Changes-Submitted-11-29-2016.pdf

In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older and over 63% were non-Caucasian comparing with 85% of Network 6 patients being 45 and over and 69% being non-Caucasian. (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59*). In 2015, over 85% of dialysis patients in Network 6 were 45 years of age and older and over 67% were non-Caucasian. (IPRO SA Network 6).

The applicant adequately demonstrates that it currently provides 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

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

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

C

In Section L, page 52, the applicant states: “*It is BMA policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.*” In Section L, page 53, the applicant projects that 81.16% of all patients in OY2 (CY2020) 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
Commercial Insurance	16.15%
Medicare	68.08%
Medicaid	3.85%
Medicare/ Commercial	9.23%
Miscellaneous (Incl. VA)	1.54%
Other: Self/Indigent/Charity	1.15%
Total	100.00%

The projected payor mix is based on the historical payor mix. The applicant adequately demonstrates that medically underserved populations will have 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.4, page 55, the applicant states *“Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. FMC Gastonia 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 Gastonia will offer a range of means by which a person can access the services. Therefore, the application is conforming to this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Section M, page 57, the applicant refers to a letter dated March 14, 2017 addressed to Gaston College which states *“Fresenius would like to invite you to include the FMC Gastonia dialysis facility in your list of facilities for clinical rotation of your nursing students.”* See Exhibit M-1. 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 six stations to the facility for a total of 33 stations upon completion of this project and Project I.D. #F-11266-16 (relocation of 12 dialysis stations from FMC Gastonia to develop the new FKC North Gaston). FMC Gastonia offers a home hemodialysis and peritoneal program.

On page 373, the 2017 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.

According to the January 2017 SDR, there are four existing dialysis facilities in Gaston County. All of the four facilities are operational, with one having been approved to relocate to another site. In addition, a fifth dialysis facility, Fresenius Kidney Center North Gaston, has been approved but is not yet developed. The applicant or its parent company owns and operates all of the four existing dialysis facilities and the fifth approved, but undeveloped, dialysis facility, in Gaston County as shown below in the table.

GASTON COUNTY DIALYSIS FACILITIES				
Certified and Approved Stations and Utilization as of June 30, 2016				
Facility	Owner	Location	Number of Existing/ Approved Stations	Utilization as of June 30, 2016
FMC Gastonia	BMA	Gastonia	39	91.03%
FMC South Gaston	BMA	Gastonia	26	95.00%
FMC Belmont	BMA	Belmont	19	87.50%
BMA Kings Mountain	BMA	Kings Mountain	16	85.94%
BMA Kings Mountain*	BMA	Kings Mountain	**18	0.00%
Fresenius Kidney Center North Gaston	BMA	Dallas	12	0.00%

Source: Table A, January 2017 SDR

*Proposed new site consisting of existing stations. **CON issued, not certified.

As shown in the table above, all four of BMA’s operational dialysis facilities are operating at or above 85% utilization. Therefore, the facilities are well utilized.

In Section N, pages 58-59, the applicant discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 58, the applicant states:

“The applicant does not expect this proposal to have effect on the competitive climate in Gaston County. The applicant does not project to serve dialysis patients currently being served by another provider. The projected patient population for the FMC Gastonia facility begins with patients currently served by BMA within the county, and a growth of that patient population consistent with the Gaston County five year annual change rate of 6.9% as published within the January 2017 SDR.”

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

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

- The applicant adequately demonstrates the need for the proposed project and that it is an effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.

- The applicant adequately demonstrates that FMC Gastonia will continue to provide quality dialysis services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- The applicant demonstrates that FMC Gastonia will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (1), (3) and (13) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

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

C

In Section B, pages 12, 14-15, Section O, pages 60-64 and Exhibit O-1, the applicant discusses the methods it uses to ensure and maintain quality. In Exhibit O-2, the applicant provides a copy of a recertification survey letter, dated January 26, 2017, for the FMC Gastonia facility which shows no condition-level deficiencies were cited.

In Section O, page 63, the applicant states that out of more than 100 facilities located in North Carolina operated by the applicant or a related entity, only the two listed below were not in compliance with Medicare conditions of participation during the 18 months prior to submission of the application.

BMA QUALITY CARE			
FACILITY	SURVEY DATE	BACK IN COMPLIANCE	
RAI West College-Warsaw	3/15/2016	Yes	4/11/2016
BMA East Rocky Mount	1/25/2017	Yes	3/2/2017

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 application is conforming with all applicable Criteria and Standards for End-Stage Renal Disease Services. The specific criteria are discussed below.

SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE 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- The applicant is not proposing to establish a new End Stage Renal Disease 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 C-1, pages 17-20, the applicant demonstrates that FMC Gastonia will serve a total of 142 in-center patients at the end of OY1 (CY2019) for a utilization rate of 107.5% or 4.3 patients per station per week ($142 \text{ patients} / 33 \text{ stations} = 4.303 / 4 = 1.075$ or 107.5%). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

-C- In Section C, pages 13-20, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.