

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 29, 2017

Findings Date: December 29, 2017

Project Analyst: Gloria C. Hale

Team Leader: Fatimah Wilson

Project ID #: F-11404-17

Facility: FMC Matthews

FID #: 080137

County: Mecklenburg

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

Project: Add 3 dialysis stations for a total of 21 stations upon completion of this project, Project I.D. #F-11241-16 (add 2 stations) and Project I.D. #F-11207-16 (relocate 5 stations to FKC Southeast Mecklenburg County)

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. d/b/a FMC Matthews proposes to add three dialysis stations to the existing facility for a total of 21 certified dialysis stations upon completion of this project, Project I.D. #F-11241-16 (add 2 stations) and Project I.D. #F-11207-16 (relocate 5 stations to FKC Southeast Mecklenburg County).

Need Determination

The 2017 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2017 Semiannual Dialysis Report (SDR), the county need methodology shows there is no county need determination for Mecklenburg County. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology

because the utilization rate reported for FMC Matthews in the July 2017 SDR is 4.48 patients per station per week. This utilization rate was calculated based on 94 in-center dialysis patients and 21 certified dialysis stations as of December 31, 2016 (94 patients /21 stations = 4.48 patients per station per week). Application of the facility need methodology indicates that eight 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 12/31/16		111.9%
Certified Stations		21
Pending Stations		2
Total Existing and Pending Stations		23
In-Center Patients as of 12/31/16 (July 2017 SDR) (SDR2)		94
In-Center Patients as of 6/30/16 (Jan 2017 SDR) (SDR1)		91
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	3
	Multiply the difference by 2 for the projected net in-center change	6
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/16	0.0659
(ii)	Divide the result of Step (i) by 12	0.0055
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/15 until 12/31/16)	0.0659
(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	100.1946
(v)	Divide the result of Step (iv) by 3.2 patients per station	31.3108
	and subtract the number of certified and pending stations to determine the number of stations needed	8.1080

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is eight stations. Rounding to the nearest whole number is allowed in Step (v) of the facility need methodology, as stated in the July 2017 SDR. 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 three new stations and, therefore, 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*. *Policy GEN-3*, on page 33, 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.”

The applicant addresses *Policy GEN-3* as follows:

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section B.4(a), page 8, Section O, pages 56-60, and Exhibit O-1. 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.4(b), page 9, Section C.3, pages 15-16, Section L, pages 48-52, and Exhibit L-1. 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.4(c) and (d), pages 9-10, Section C, page 17, and Section N, page 54. 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.

Conclusion

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant’s use of the facility need methodology in accordance with the July 2017 SDR.
- The applicant’s use of existing policies, historical data, and verifiable sources to provide future projections and demonstrate conformity with Policy GEN-3.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

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

C

Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Matthews proposes to add three dialysis stations to the existing facility for a total of 21 certified dialysis stations upon completion of this project, Project I.D. #F-11241-16 (add 2 stations) and Project I.D. #F-11207-16 (relocate 5 stations to FKC Southeast Mecklenburg County).

Patient Origin

On page 373, the 2017 SMFP defines the service area for dialysis stations as *“the 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 counties is a separate dialysis station planning area.”* Thus, the service area is Mecklenburg County. Facilities may serve residents of counties not included in their service area.

In Section C.8, page 17, the applicant provides the historical in-center patient origin for FMC Matthews as of June 30, 2017, which is summarized in the following table:

**FMC Matthews
Historical Patient Origin
June 30, 2017**

County	In-Center Patients
Mecklenburg	80
Union	17
Other States	3
TOTALS	100

In clarifying information, the applicant provides the projected patient origin for FMC Matthews for operating year one (OY1), Calendar Year (CY) 2019, and OY2, CY2020, following completion of the project, as follows:

**FMC Matthews
 Projected In-Center Patient Origin***

County	OY1	OY2	County Patients as Percent of Total	
			OY1	OY2
Mecklenburg	89.6	94.2	91.8%	92.2%
Union	8.0	8.0	8.2%	7.8%
Total	97.6	102.2	100.0%	100.0%

*Calculated by Project Analyst based on clarifying information provided by the applicant.

**Total may not foot due to rounding.

The applicant provides the assumptions used to project in-center patient origin in Section C.1, pages 13-14. The applicant provides the methodology used to project in-center patient origin in clarifying information. The applicant adequately identifies the population to be served.

Analysis of Need

In Section B.4, page 8, the applicant states the application is filed pursuant to the facility need methodology in the 2017 SMFP, and utilizes data from the July 2017 SDR to apply the facility need methodology provided in Section B.2, page 6, to demonstrate how the facility qualifies for three additional stations. In Section C.1, pages 13-14, the applicant provides the following assumptions for projecting in-center patients:

1. The current patient population at FMC Matthews and who reside in Mecklenburg County are a part of the Mecklenburg County ESRD patient population as a whole and as such will increase at the Five Year Average Annual Change Rate (AACR) for Mecklenburg County of 5.1% as published in the July 2017 SDR.
2. Two patients, one from Mecklenburg County and one from Union County, are projected to transfer from FMC Matthews to Fresenius Kidney Care (FKC) Southeast Mecklenburg County (Project I.D. #F-11207-16) upon completion of that project. FKC Southeast Mecklenburg County is expected to be certified by June 30, 2018, therefore two patients will be subtracted as of June 30, 2018.
3. Eight of 17 patients from Union County are projected to continue dialyzing at FMC Matthews as a matter of patient choice. These nine patients are added at appropriate points in the methodology.
4. Eight of the 17 patients from Union County are expected to transfer their care to FKC Indian Trail upon completion of that project by June 30, 2018. Therefore, these eight patients will be subtracted by June 30, 2018.

5. Three patients from other states, assumed to be transient patients, were being served at FMC Matthews as of June 30, 2017. These three patients will not be carried forward in the methodology.
6. The project is scheduled to be completed by December 31, 2018.
7. The first two operating years for the proposed project will be CY2019 and CY2020.

Projected Utilization

The applicant provides its methodology for projecting utilization for in-center patients for OY1 and OY2, in clarifying information, as follows:

	In-Center Patients
The applicant begins with the Mecklenburg County in-patient census at the facility on June 30, 2017.	80
The Mecklenburg County in-center patient census is projected forward six months to December 31, 2017, increased by one-half the Five Year AACR for Mecklenburg County of 5.1%.	$80 \times 1.0255 = 82.04$
The Mecklenburg County in-center patient census is projected forward six months to June 30, 2018, increased by one-half the Five Year AACR for Mecklenburg County of 5.1%.	$82.04 \times 1.0255 = 84.10$
The applicant subtracts one in-center Mecklenburg County patient projected to transfer to FKC Southeast Mecklenburg County.	$84.10 - 1 = 83.10$
The census of Mecklenburg County in-center census is projected forward to December 31, 2018, increased by one-half the Five Year AACR for Mecklenburg County of 5.1%.	$83.10 \times 1.0255 = 85.30$
Eight of 17 patients from Union County are added (nine are transferring: one to FKC Southeast Mecklenburg County and eight to FKC Indian Trail.) This is the beginning census of the project.	$85.30 + 8 = 93.30$
The census of Mecklenburg County in-center patients only is projected forward one year and increased by the Five Year AACR for Mecklenburg County of 5.1% to December 31, 2019.	$85.30 \times 1.051 = 89.60$
The applicant adds eight patients from Union County. This is the ending census for OY1.	$89.60 + 8 = 97.60$
The census of Mecklenburg County in-center patients only is projected forward one year and increased by the Five Year AACR for Mecklenburg County of 5.1% to December 31, 2020.	$89.60 \times 1.051 = 94.20$
The applicant adds eight patients from Union County. This is the ending census for OY2.	$94.20 + 8 = 102.20$

The applicant states, in clarifying information, that it projects to serve 97 in-center patients, rounded down from 97.60, by the end of OY1 which is 4.62 patients per station per week ($97 \text{ patients} / 21 \text{ dialysis stations} = 4.62$). Therefore, the applicant's projected utilization exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

In summary, the applicant adequately identifies the patient origin and adequately demonstrates the need for three additional dialysis stations at FMC Matthews.

Access

In Section C.3, pages 15-16, the applicant states that BMA has a long history of serving the underserved population in the state and that each facility serves “*low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.*” In addition, the applicant states that it is corporate policy to provide services to all patients regardless of income or any other factor that would deem them to be underserved. In Section L.7, page 52, the applicant states that 79.9% of FMC Matthews’s patients were Medicare recipients in CY2016. The applicant states that FMC Matthews does accept Medicaid patients, however in CY2016, facility accounting showed that the facility returned revenues to Medicaid which the applicant states would have been a result of overpayment or incorrect billing. In Section L.1, page 49, the applicant projects that 78.2% of all of FMC Matthews’ patients will be Medicare or Medicaid recipients. The applicant adequately demonstrates the extent to which all residents of the service area, including underserved groups, are likely to have access to its services.

Conclusion

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant uses historical data that is clearly cited and is reasonable to use to make the assumptions used by the applicant with regard to identifying the population to be served and with regard to demonstrating the need the population projected to be served has for the proposed services.
- The applicant uses established methodologies and uses assumptions which are reasonable to demonstrate the need the population projected to be served has for the proposed services.
- The applicant uses historical data to project future access to the services it provides for all residents, including underserved groups.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that 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

The applicant does not propose to reduce, eliminate or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

- (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 21, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

- Maintain the Status Quo –The applicant states that the facility’s projected utilization will be greater than 80% at the end of OY1, therefore maintaining the status quo would result in higher utilization rates and potentially cause admissions to be restricted. Therefore, this is not the most effective alternative.
- Apply for Fewer Stations – The applicant states that based on the facility need methodology it could have applied for eight dialysis stations, however due to space constraints, it is only applying for three. The applicant states that the facility is continuing to grow and will exceed 100% utilization even with the three dialysis stations proposed. Therefore, this is not the most effective alternative.
- Include Home Therapies – The applicant states that it could have proposed to include home therapies at the facility, however there is not enough space to do so. Therefore, this is not the most effective alternative.
- Relocate Stations to FMC Matthews – The applicant states it considered relocating dialysis stations from other BMA facilities in Mecklenburg County to FMC Matthews, however all of the other facilities are operating at over 80% of capacity. Therefore, this is not the most effective alternative.

In Section C.2, page 15, the applicant states that the projected population at FMC Matthews has a need for the additional stations and that “*failure to add these three stations will lead to higher utilization rates at the facility.*” Therefore, the proposed alternative represented in the application and in supplemental information is the most effective alternative to meet the identified need.

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.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant uses reasonable and adequately supported assumptions to project utilization.

- The data cited is reasonable to use to support the assumptions of the applicant with regard to the least costly or most effective alternative for development of the proposed project.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion and is approved subject to the following conditions.

- 1. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Matthews shall materially comply with all representations made in the certificate of need application and any supplemental responses. In the event that representations conflict, Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Matthews shall materially comply with the last made representation.**
 - 2. Pursuant to the facility need determination in the July 2017 SDR, Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Matthews shall develop and operate no more than three additional dialysis stations for a total of no more than 21 certified stations upon completion of the project and Project I.D. #F-11241-16 (add 2 stations) and Project I.D. #F-11207-16 (relocate 5 stations to FKC Southeast Mecklenburg County).**
 - 3. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Matthews shall install plumbing and electrical wiring through the walls for three additional dialysis stations for a total of no more than 21 dialysis stations which shall include any isolation stations.**
 - 4. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Matthews 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

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Capital and Working Capital Costs

In Section F.1, page 24, the applicant states that there will be no capital cost for the project. In Sections F.10-F.12, page 26, the applicant states there will be no start-up expenses or initial operating expenses incurred for this project since FMC Matthews is an existing facility.

Financial Feasibility

The applicant provides pro forma financial statements for the first two years of the project in supplemental information. In the applicant's assumptions for Form C of the pro formas, the applicant states that it calculated the average annual number of patients for the first two operating years of the project, rounded down, to calculate the in-center patient revenues. Thus, for OY1 the applicant projects to begin with 93.3 patient and end with 97.6 patients for an average of 95 in-center patients. Similarly for OY2 the applicant projects to begin with 97.6 patients and end with 102.2 patients for an average of 99 in-center patients.

In clarifying information, the applicant provides pro forma financial statements for the first two operating years of the project following completion. In Form B, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

FMC Matthews		
	OY1 (CY2019)	OY2 (CY2020)
Total Treatments	14,079	14,671
Total Gross Revenues (Charges)	\$ 56,147,052	\$ 58,507,948
Deductions from Gross Revenues	\$ 50,689,687	\$ 52,821,109
Total Net Revenue	\$ 5,457,365	\$ 5,686,839
Total Operating Expenses (Costs)	\$ 3,812,160	\$ 3,932,005
Net Income	\$ 1,645,205	\$ 1,754,835

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See the supplemental information 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 upon reasonable projections of costs and charges.

Conclusion

The information in the application and supplemental information, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant uses reasonable and adequately supported assumptions to project utilization.
- No working capital is needed since the facility is existing and operational.
- No funding is needed for capital costs.

- The applicant projects that revenues will exceed operating expenses in the first two operating years of the project.

This determination is based on a review of the information in the application, including any exhibits.

Therefore, the applicant adequately demonstrates that 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

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On page 373, the 2017 SMFP defines the service area for dialysis stations as *“the 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 counties is a separate dialysis station planning area.”* Thus, the service area is Mecklenburg County. Facilities may serve residents of counties not included in their service area.

According to the July 2017 SDR, there are 23 dialysis facilities in Mecklenburg County, 17 of which are operational. Information on all 23 of these dialysis facilities, from Table B of the July 2017 SDR, is provided below:

**Mecklenburg County Dialysis Facilities
 Certified Stations and Utilization as of December 31, 2016**

Dialysis Facility	Owner	Location	Number of Certified Stations	Utilization
BMA Beatties Ford	BMA	Matthews	32	98.44%
BMA Nations Ford	BMA	Matthews	28	93.75%
BMA of East Matthews	BMA	Matthews	25	92.00%
BMA of North Matthews	BMA	Matthews	36	102.78%
BMA West Matthews	BMA	Matthews	29	86.21%
Brookshire Dialysis	DaVita	Matthews	0	0.00%
Carolinas Medical Center	CMC	Matthews	9	27.78%
Matthews Dialysis	DaVita	Matthews	36	84.72%
Matthews East Dialysis	DaVita	Matthews	34	88.24%
DSI Matthews Latrobe Dialysis	DSI	Matthews	24	69.79%
DSI Glenwater Dialysis	DSI	Matthews	42	77.38%
FMC Matthews	BMA	Matthews	43	90.70%
FMC Matthews	BMA	Matthews	21	111.90%
FKC Southeast Mecklenburg County**	BMA	Matthews	0	0.00%
FMC Regal Oaks*	BMA	Matthews	0	0.00%
FMC Aldersgate*	BMA	Matthews	0	0.00%
Fresenius Medical Care Southwest Matthews***	BMA	Matthews	10	40.00%
Huntersville Dialysis	DaVita	Huntersville	10	92.50%
Mint Hill Dialysis	DaVita	Mint Hill	16	96.88%
North Matthews Dialysis Center	DaVita	Matthews	41	74.39%
South Matthews Dialysis	DaVita	Matthews	22	86.36%
South Matthews Dialysis*	DaVita	Matthews	0	0.00%
Sugar Creek Dialysis*	DaVita	Matthews	0	0.00%

Source: July 2017 SDR, Table B.

* Facility under development.

** FKC Southeast Mecklenburg County is a new facility under development, however it is erroneously named FMC of Southwest Matthews in the July 2017 SDR, Table B. In addition, the FID# should be 160337.

*** FMC Southwest Matthews is an existing facility, however the FID# is erroneous as listed in the July 2017 SDR, Table B. The FID# should be 120485.

As illustrated above, BMA owns eight of the 17 operational dialysis facilities in Mecklenburg County. As shown in the table above, seven of BMA's eight operational dialysis facilities are operating above 80% utilization (3.2 patients per station per week) and six of those are operating above 90% utilization. Five dialysis facilities are operating below 80% utilization, including one BMA facility, two DSI facilities, a CMC facility, and one DaVita facility. The BMA facility that is operating below 80% utilization at 40% is FMC Southwest Matthews, however it is newly operational and has 10 dialysis stations, the minimum number of dialysis stations allowed. Therefore, dialysis stations cannot be relocated to FMC Matthews to address the need for additional dialysis stations at that facility.

According to Table D in the July 2017 SDR, there is a surplus of fourteen dialysis stations in Mecklenburg County. The applicant proposes to add three dialysis stations for a total of 21 dialysis stations upon completion of the project. However, the applicant is applying for additional stations based on the facility need methodology. According to Table B in the July 2017 SDR, as of December 31, 2016 FMC Matthews was serving 94 patients on 21 dialysis stations per week, which is 4.48 patients per station per week or 111.9% of capacity. The applicant does not propose to establish a new facility. In supplemental information, the applicant adequately demonstrates that FMC Matthews will serve a total of 97 in-center patients on 21 dialysis stations at the end of OY1 (CY2019), for a utilization rate of 4.62 patients per station per week, or 115% of capacity ($97/21 = 4.62$; $4.62/4 = 115\%$). Therefore, the facility is expected to serve more than 3.2 patients per station per week at the end of the first operating year as required by 10A NCAC 14C .2203(b). The applicant adequately demonstrates the need to add three additional dialysis stations at the existing facility based on the number of in-center patients it proposes to serve.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant is not proposing to develop a new dialysis facility, rather it is proposing to add dialysis stations to the existing facility based on the facility need methodology.
- All other operational BMA dialysis facilities in Mecklenburg County, with the exception of Fresenius Medical Care Southwest Charlotte which is a new facility, are operating at over 80% of capacity.
- The applicant expects to serve more than 3.2 patients per station per week at the end of the first operating year as required by 10A NCAC 14C .2203(b).

This determination is based on a review of the:

- Information in the application, including any exhibits, and
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that 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.1, page 35, the applicant provides the current and projected staffing for the facility, which will remain at 24.45 full-time equivalent (FTE) employees upon completion of the proposed project. Projected direct care staff in OY2, from Section H.7, page 37, is shown in the following table:

**FMC Matthews
Projected Direct Care Staff Hours
OY2**

Direct Care Positions	# of FTEs	Hours per Year per FTE	Total Annual FTE Hours	Total Annual Hours of Operation	#FTE Hours per Hour of Operation
RN	6	2,080	12,480	4,212	2.96
LPN	1	2,080	2,080	4,212	0.49
Patient Care Technician	12	2,080	24,960	4,212	5.93
Total	19	2,080	39,520	4,212	9.38

In Section H.6, page 40, the applicant states that dialysis services will be available from 6:00 a.m. to 10:00 p.m., Monday, Wednesday and Friday, and 6:00 a.m. to 5:00 p.m. on Tuesday, Thursday, and Saturday.

In Section H.3, pages 35-36, the applicant states that it employs aggressive recruiting and advertising efforts to hire staff, along with providing a range of benefits and competitive salaries to attract and maintain staff. Exhibit I-5 contains a copy of a letter from Edward Carl Fisher, Jr., M.D., stating his support for the project and his willingness to continue serving as the Medical Director for the facility.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant provides appropriate documentation of the availability of adequate health manpower and management personnel for the provision of the proposed dialysis services.
- The applicant provides appropriate and credible documentation of support from the current and continuing Medical Director of FMC Matthews.
- The applicant provides appropriate and credible documentation of the availability of other resources, including methods of recruitment and documentation of staff training, necessary for the provision of the proposed dialysis services.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that 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.1, page 38, the applicant includes a list of providers of the necessary ancillary and support services. Exhibits I-2, I-3 and I-4 contain copies of agreements with providers for laboratory services, hospital services, and transplants, respectively.

In Section I.3, page 40, the applicant provides a listing of nephrologists at Metrolina Nephrology Associates who have agreed to provide medical coverage at the facility and who have expressed support for the project. In addition, the applicant states, on page 41, that BMA has informal relationships with other physicians in the area. Moreover, Exhibit I-5 contains a letter from the medical director of the facility that expresses his support for the proposed project.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- A list of current and projected necessary ancillary and support services, and who will be providing them, is included.
- The applicant identifies nephrologists in the area who have agreed to provide medical coverage at the facility, and
- The facility's medical director has provided a letter of support.

This determination is based on a review of the information in the application, including any exhibits.

Therefore, the applicant adequately demonstrates that 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

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion 9 is not applicable to this review.

- (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

The applicant is not an HMO. Therefore, Criterion 10 is not applicable to this review.

- (11) Repealed effective January 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

The applicant does not propose to construct any new space nor renovate any existing space. Therefore, Criterion 12 is not applicable to this review.

- (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.7, page 52, the applicant reports that 79.9% of the in-center patients who received treatments at FMC Matthews in CY2016 had some or all of their services paid for by Medicare. The applicant states that the facility returned revenues to Medicaid as a result of overpayment or potentially incorrect billing. The table below,

from page 52 of the application, provides the historical (CY2016) payment source for FMC Matthews' patients:

Payment Source	Total Facility
Self-Pay/Indigent/Charity	2.96%
Commercial Insurance	15.08%
Medicare	63.47%
Medicaid	-0.76%
Misc., including VA	2.05%
Medicare/Commercial Insurance	5.10%
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.

County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
Mecklenburg	10%	52%	51%	15%	6%	19%
Statewide	15%	51%	36%	17%	10%	15%

Source: <http://www.census.gov/quickfacts/table>, 2014 Estimate as of December 22, 2015.

*Excludes "White alone" who are "not Hispanic or Latino"

**"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consists of North Carolina, South Carolina and Georgia. IPRO SA Network 6 provides a 2015 Annual Report which includes aggregate ESRD patient data from all three states. However, a comparison of the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report*¹ percentages for North Carolina and the aggregate data for all three states in IPRO SA Network 6 shows very little variance; therefore the statistics for IPRO SA Network 6 are representative of North Carolina.

The IPRO SA Network 6 provides prevalence data on dialysis patients by age, race, and gender in its 2015 annual report, pages 27-28². In 2015, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 67% were non-Caucasian and 45% were female. (IPRO SA Network 6).

¹<http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf>

²http://esrd.ipro.org/wp-content/uploads/2016/11/2015_NW-6_Annual-Report_Final-Draft-with-COR-Changes-Submitted-11-29-2016.pdf

The information in the application, including any exhibits, is reasonable and adequately supported because 80% of FMC Charlotte's dialysis patients were Medicare recipients in CY2016.

This determination is based on a review of the:

- Information in the application, including any applicable exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that 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.3, page 50, the applicant states:

“BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations.

...

The applicant will treat all patients the same regardless of race or handicap status.”

In Section L.6, page 51, the applicant states there have been no civil rights complaints filed against any BMA North Carolina facility in the past five years.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant does not have any obligation to provide uncompensated care or community service under any federal regulations, and
- The applicant states that no BMA North Carolina facility has had any civil rights complaints filed against it in the past five years.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that 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.1(b), page 49, the applicant projects that 78.2% of all patients who will receive treatments at FMC Matthews in OY2, CY2020, will have some or all of their services paid for by Medicare or Medicaid. The table below, from page 49 of the application, shows the projected OY2 payor mix for the facility for all patients:

**FMC Matthews
Projected Payor Mix, OY2 (CY2020)**

Payment Source	Percent of All Patients
Self-Pay/Indigent/Charity	2.15%
Commercial Insurance	17.36%
Medicare	59.45%
Medicaid	0.67%
Miscellaneous (incl. VA)	2.32%
Medicare/Commercial Insurance	18.06%
Total	100.00%

In supplemental information, the applicant provides the assumption used to project payor mix, stating that it is based on the facility's recent performance.

The information in the application, including any exhibits, is reasonable and adequately supported because the applicant projects that 78.2% of its dialysis patients will be Medicare or Medicaid recipients based on historical payor mix of the facility.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that 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 51, the applicant describes the range of means by which a person will have access to the dialysis services at FMC Matthews, stating that any nephrologist may apply for privileges to admit patients and receive referrals from other nephrologists, other physicians, or hospital emergency rooms. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to dialysis services.

The information in the application, including any exhibits, is reasonable and adequately supported because the applicant states that patients will be admitted for dialysis through physicians with admitting privileges.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that 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.1, page 53, the applicant states that BMA has communicated with local educational nursing programs, inviting their students to utilize FMC Matthews as an instructional site. Exhibit M-1 contains a copy of a letter to Central Piedmont Community College offering FMC Matthews as a clinical training site for the college's nursing students.

The information in the application, including any exhibits, is reasonable and adequately supported because the applicant has demonstrated its intent to offer the facility as a clinical training site.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

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

C

Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Matthews proposes to add three dialysis stations to the existing facility for a total of 21 certified dialysis stations upon completion of this project, Project I.D. #F-11241-16 (add 2 stations) and Project I.D. #F-11207-16 (relocate 5 stations to FKC Southeast Mecklenburg County).

On page 373, the 2017 SMFP defines the service area for dialysis stations as *“the 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 counties is a separate dialysis station planning area.”* Thus, the service area is Mecklenburg County. Facilities may serve residents of counties not included in their service area.

According to the July 2017 SDR, there are 23 dialysis facilities in Mecklenburg County, 17 of which are operational. Information on all 23 of these dialysis facilities, from Table B of the July 2017 SDR, is provided below:

**Mecklenburg County Dialysis Facilities
 Certified Stations and Utilization as of December 31, 2016**

Dialysis Facility	Owner	Location	Number of Certified Stations	Utilization
BMA Beatties Ford	BMA	Matthews	32	98.44%
BMA Nations Ford	BMA	Matthews	28	93.75%
BMA of East Matthews	BMA	Matthews	25	92.00%
BMA of North Matthews	BMA	Matthews	36	102.78%
BMA West Matthews	BMA	Matthews	29	86.21%
Brookshire Dialysis	DaVita	Matthews	0	0.00%
Carolinas Medical Center	CMC	Matthews	9	27.78%
Matthews Dialysis	DaVita	Matthews	36	84.72%
Matthews East Dialysis	DaVita	Matthews	34	88.24%
DSI Matthews Latrobe Dialysis	DSI	Matthews	24	69.79%
DSI Glenwater Dialysis	DSI	Matthews	42	77.38%
FMC Matthews	BMA	Matthews	43	90.70%
FMC Matthews	BMA	Matthews	21	111.90%
FKC Southeast Mecklenburg County**	BMA	Matthews	0	0.00%
FMC Regal Oaks*	BMA	Matthews	0	0.00%
FMC Aldersgate*	BMA	Matthews	0	0.00%
Fresenius Medical Care Southwest Matthews***	BMA	Matthews	10	40.00%
Huntersville Dialysis	DaVita	Huntersville	10	92.50%
Mint Hill Dialysis	DaVita	Mint Hill	16	96.88%
North Matthews Dialysis Center	DaVita	Matthews	41	74.39%
South Matthews Dialysis	DaVita	Matthews	22	86.36%
South Matthews Dialysis*	DaVita	Matthews	0	0.00%
Sugar Creek Dialysis*	DaVita	Matthews	0	0.00%

Source: July 2017 SDR, Table B.

* Facility under development.

** FKC Southeast Mecklenburg County is a new facility under development, however it is erroneously named FMC of Southwest Matthews in the July 2017 SDR, Table B. In addition, the FID# should be 160337.

*** FMC Southwest Matthews is an existing facility, however the FID# is erroneous as listed in the July 2017 SDR, Table B. The FID# should be 120485.

As illustrated above, BMA owns eight of the 17 operational dialysis facilities in Mecklenburg County. As shown in the table above, seven of BMA's eight operational dialysis facilities are operating above 80% utilization (3.2 patients per station per week) and six of those are operating above 90% utilization. Five dialysis facilities are operating below 80% utilization, including one BMA facility, two DSI facilities, a CMC facility, and one DaVita facility.

In Section N.1, page 54, the applicant discusses how any enhanced competition will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states,

“BMA facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid. ...In this application, BMA projects that greater than 78% of the In-center patients will be relying upon government payors (Medicare /Medicaid). The facility must capitalize upon every opportunity for efficiency.

...

This proposal will certainly not adversely affect quality, but rather, enhance the quality of the ESRD patients’ lives by offering another convenient venue for dialysis care and treatment.”

See also Sections B, C, F, K, L, N and O where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The applicant discusses how any enhanced competition in the service area, including how the proposed project will have a positive impact on cost-effectiveness, quality and access to the proposed services in Section N, page 54. The information in the application is reasonable and adequately supported for the following reasons:

- The applicant adequately demonstrates the need for the proposed project and that it is an effective alternative.
- The applicant adequately demonstrates that FMC Matthews will continue to provide quality dialysis services.
- The applicant demonstrates that FMC Matthews will continue to provide adequate access to medically underserved populations.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

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

In Exhibit A-4, the applicant identifies the kidney disease treatment centers located in North Carolina that it or an affiliated company owns and operates. In Section O.3, pages 59-60, the applicant identifies two of its facilities, BMA East Rocky Mount, and RAI West College Warsaw, that were cited in the past 18 months for deficiencies in compliance with 42 CFR Part 494, the Centers for Medicare and Medicaid (CMS) Conditions for Coverage of ESRD facilities. The applicant provides documentation regarding the deficiencies and subsequent compliance with CMS Conditions for Coverage in Exhibits O-2, O-3, and O-4. The applicant states, on page 60, that all three facilities are back in full compliance with CMS Guidelines as of the date of submission of this application. Based on a review of the certificate of need application and publicly available data, 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 information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant provides adequate and credible documentation of its current policies with regard to providing quality care.
- The applicant provides accurate information regarding past deficiencies and how those deficiencies were addressed.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

(21) Repealed effective January 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 promulgated in 10A NCAC 14C .2200. The specific criteria are 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- The applicant is proposing to add dialysis stations to an existing facility, FMC Matthews. Therefore, this performance standard is not applicable.

.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 supplemental information, the applicant documents the need for the project and demonstrates that it will serve 97 in-center patients by the end of OY1, which is 4.62 patients per station per week ($97/21 = 4.62$). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

-C- In Section C.1, pages 13-14, the applicant provides the assumptions used to project utilization of the facility. In supplemental information, the applicant provides the methodology used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant provides adequate and credible documentation that it meets the performance standard required by this Rule.
- The applicant provides all documentation of its assumptions and methodology required by this Rule.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.