

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: July 19, 2017

Findings Date: July 19, 2017

Project Analyst: Gregory F. Yakaboski

Team Leader: Lisa Pittman

Project ID #: F-11345-17

Facility: FMC Southwest Charlotte

FID #: 120485

County: Mecklenburg

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

Project: Relocate three dialysis stations from FMC Charlotte to FMC Southwest Charlotte for a total of 13 stations at FMC Southwest Charlotte upon completion of this project.

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 Southwest Charlotte (FMC Southwest Charlotte and/or the facility) proposes to relocate three dialysis stations from FMC Charlotte to FMC Southwest Charlotte for a total of 13 dialysis stations at FMC Southwest Charlotte upon completion of this project. FMC Charlotte will have a total of 41 dialysis stations upon completion of this project and Project I.D. #F-11306-17 (add 7 stations) and Project I.D. #F-11099-15 (relocate six stations to FMC Aldersgate). FMC Southwest Charlotte offers a home hemodialysis and peritoneal program.

Need Determination

The proposed project is to relocate existing dialysis stations between facilities. Therefore, neither the county need nor the facility need methodologies in the 2017 State Medical Facilities Plan (2017 SMFP) are applicable to this review. Additionally, Policy GEN-3: *Basic Principles* is not applicable because neither need methodology is applicable to the review.

Policies

The following policy is applicable to this review:

- POLICY ESRD-2: RELOCATION OF DIALYSIS STATIONS

POLICY ESRD-2: RELOCATION OF DIALYSIS STATIONS states:

“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties. Certificate of need applicants proposing to relocate dialysis stations to a contiguous county shall:

- 1. Demonstrate that the facility losing dialysis stations or moving to a contiguous county is currently serving residents of that contiguous county; and*
- 2. Demonstrate that the proposal shall not result in a deficit, or increase an existing deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*
- 3. Demonstrate that the proposal shall not result in a surplus, or increase an existing surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.”*

BMA is proposing to relocate existing dialysis stations within Mecklenburg County, therefore the proposed project is in compliance with Policy ESRD-2- *Relocation of Dialysis Stations*.

Conclusion

In summary, the applicant adequately demonstrates that the proposal is consistent with the Policy ESRD-2. 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 relocate three dialysis stations from FMC Charlotte to FMC Southwest Charlotte for a total of 13 dialysis stations upon completion of this project. FMC Southwest Charlotte 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 Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

In Section C, page 21, the applicant provides a table showing the historical patient origin for both in-center (IC) patients, home hemodialysis (HH) patients and peritoneal (PD) patients served by FMC Southwest Charlotte, as shown below:

Dialysis Patients as of 4/30/17

COUNTY	IC	HH	PD
Mecklenburg	28	1	2
Union	0	0	1
South Carolina	4	0	0
Totals	32	1	3

In Section C, page 16, 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 CY2018			OPERATING YEAR 2 CY2019			COUNTY PATIENTS AS % OF TOTAL	
	IC	HH	PD	IC	HH	PD	OY 1	OY 2
Mecklenburg	40.8	1	2	42.8	1	2	89.8%	90.2%
Union	0	0	1	0	0	1	2.0%	2.0%
South Carolina	4	0	0	4	0	0	8.2%	7.8%
Totals	44	1	3	46	1	3	100.0%	100.0%

The applicant provides the assumptions and methodology for the projections above on pages 16-18. The applicant adequately identifies the population it proposes to serve.

Analysis of Need

In Section C, pages 16-18, BMA states the need for the proposed project is based on ten existing patients who are currently dialyzing at two existing BMA facilities in Mecklenburg County, FMC Charlotte and BMA Nations Ford, and who are considering transferring their care to another BMA facility, FMC Southwest Charlotte, which is physically closer to where they reside. The ten existing BMA patients have each submitted a letter stating that they will consider transferring their case to FMC Charlotte as it would improve their access to care through ease of transportation to the dialysis facility. See Exhibit C-1. FMC Charlotte is the facility from which the three dialysis stations are proposed to be transferred from to FMC Southwest Charlotte.

Projected Utilization- IC Patients

In Section C, page 16, the applicant provides projected utilization during the first two years of operation following project completion, as illustrated in the table below:

COUNTY	OPERATING YEAR 1 CY2018			OPERATING YEAR 2 CY2019			COUNTY PATIENTS AS % OF TOTAL	
	IC	HH	PD	IC	HH	PD	OY 1	OY 2
Mecklenburg	40.8	1	2	42.8	1	2	89.8%	90.2%
Union	0	0	1	0	0	1	2.0%	2.0%
South Carolina	4	0	0	4	0	0	8.2%	7.8%
Totals	44	1	3	46	1	3	100.0%	100,0%

In Section C, pages 16-18, the applicant provides the assumptions and methodology used to project utilization. On page 17, the applicant provides a table illustrating how utilization was projected, which is summarized below:

- Operating Year 1 = Calendar Year 2018 (CY2018)
- Operating Year 2 = Calendar Year 2019 (CY2019)
- BMA states that to project annual growth of the in-center patients who are residents of Mecklenburg County it applied the Five Year Average Annual Growth Rate (AAGR) for Mecklenburg County (5.0%) published in the January 2017 SDR.
- As of December 31, 2016, based on the ESRD Data collection form, FMC Southwest Charlotte had 16 IC patients. As of April 30, 2017, FMC Southwest Charlotte had 32 IC patients. Based on the doubling of the IC patient census in the four months from December 31, 2016 to April 30, 2017, BMA is assuming the patient growth at FMC Southwest Charlotte will exceed the 5.0% AAGR of Mecklenburg County. In projecting utilization for IC patients for the proposed project BMA utilized the 5.0% AAGR of Mecklenburg County.

- Based on letters of support, BMA is projecting 10 existing BMA patients currently dialyzing at a different BMA facility in Mecklenburg County will transfer to FMC Southwest Charlotte upon project completion.
- FMC Southwest Charlotte had 32 in-center patients as of April 30, 2017. Four of the 32 in-center patients were not from Mecklenburg County. Those four patients were from South Carolina. In projecting utilization no growth calculations were performed on the four in-center patients dialyzing at FMC Southwest Charlotte who were not residents of Mecklenburg County.

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

Begin with the 28 in-center patients from Mecklenburg County utilizing FMC Southwest Charlotte as of April 30, 2017.	28
Project this Mecklenburg County patient population forward for eight months to December 31, 2017 using the 5.0% AAGR	$1.033 \times 28 = 28.9$
Add the 10 patients residing in Mecklenburg County at other BMA facilities and expected to transfer their care to the FMC Southwest Charlotte upon project completion.	$28.9 + 10 = 38.9$
Add the 4 patients who reside in South Carolina currently dialyzing at FMC Southwest Charlotte. This is the starting census for Operating Year 1.	$38.9 + 4 = 42.9$
Project the Mecklenburg County patient population forward for one year to December 31, 2018 using the 5.0% AAGR	$1.05 \times 38.9 = 40.8$
Add in the 4 patients who reside in South Carolina currently dialyzing at FMC Southwest Charlotte. This is the projected ending census for Operating Year 1 (CY2018).	$40.8 + 4 = \mathbf{44.8}$
Project the Mecklenburg County patient population forward for one year to December 31, 2019 using the 5.0% AAGR	$1.05 \times 40.8 = 42.8$
Add in the 4 patients who reside in South Carolina currently dialyzing at FMC Southwest Charlotte. This is the projected ending census for Operating Year 2 (CY2019).	$42.8 + 4 = \mathbf{46.8}$

Projected patients for OY1 and OY2 are rounded down to the nearest whole number. Therefore, at the end of OY1 (CY 2018) the facility is projected to serve 44 in-center patients and at the end of OY2 (CY2019) the facility is projected to serve 46 in-center patients.

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

- OY1: 3.38 patients per station per week or 84.5% ($44 \text{ patients} / 13 \text{ stations} = 3.38 / 4 = 0.845$ or 84.5%).
- OY2: 3.538 patients per station per week or 88.45% ($46 \text{ patients} / 13 \text{ stations} = 3.538 / 4 = 0.8845$ or 88.45%).

The projected utilization of 3.38 patients per station per week at the end of OY1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

Projected Utilization- HH and PD Patients

As of April 30, 2017, the FMC Southwest Charlotte had four patients utilizing home hemodialysis or peritoneal dialysis. On page 18, the applicant states that while the number of patients in the home therapies program was expected to increase, for purposes of the application the home patient population was projected to remain constant.

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

Access

In Section L, pages 54-55, 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. In Section L, page 58, the applicant reports that 80.0% of the patients who received treatments at FMC Southwest Charlotte had some or all of their services paid for by Medicare or Medicaid during the approximate thirty eight days the facility was operational in 2016. The table below shows the historical payment sources of the facility from 11/23/16 to 12/31/16.

FMC Southwest Charlotte

Payment Source	Percent of Total Patients
Commercial Insurance	16.0%
Medicare	74.0%
Medicaid	2.0%
Medicare/ Commercial	4.0%
Miscellaneous (Incl. VA)	2.0%
Other: Self/Indigent/Charity	2.0%
Total	100.00%

On page 58, the applicant also provided the historical payor source data for FMC Charlotte, the facility from which the three dialysis stations are being relocated, which demonstrated that 75.15% of the patients who received treatments at FMC Charlotte during CY2016 had some or all of their services paid for by Medicare or Medicaid.

FMC Charlotte

Payment Source	Percent of Total Patients
Commercial Insurance	21.27%
Medicare	64.77%
Medicaid	5.29%
Medicare/ Commercial	5.09%
Miscellaneous (Incl. VA)	1.47%
Other: Self/Indigent/Charity	2.11%
Total	100.00%

The applicant projects 80.0% of its patients will be Medicare or Medicaid recipients in OY2 (CY2018). 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.

C

BMA proposes to relocate three dialysis stations from FMC Charlotte to FMC Southwest Charlotte for a total of 13 dialysis stations upon completion of this project. FMC Southwest Charlotte offers a home hemodialysis and peritoneal program.

In Section D, pages 26 - 27, the applicant states that as of December 31, 2016, there were 156 in-center dialysis patients dialyzing at FMC Charlotte. According to the July 2017 SDR FMC Charlotte had 43 certified dialysis stations as of December 31, 2016, for a utilization rate of 90.70% [$156 / 43 = 3.6279$; $3.63 / 4 = .9069$ or 90.70%]. Of the 156 patients, the applicant states that 149 were residents of Mecklenburg County, as shown in the following table:

FMC Charlotte 12/31/16

COUNTY	# PATIENTS
Mecklenburg	149
Gaston	1
Union	3
South Carolina	1
Other States	2
Total	156

The applicant proposes to relocate three stations from FMC Charlotte to FMC Southwest Charlotte. The applicant assumes that the number of Mecklenburg County residents dialyzing at FMC Charlotte will increase at 5.0% per year based on the Five Year AACR for Mecklenburg County, as reported in Table B of the January 2017 SDR. In Section D.1, page 27, the applicant calculates the in-center patient census for FMC Charlotte through December 31, 2017, the projected certification date for the relocated stations at FMC Southwest Charlotte, as illustrated in the following table:

Begin with Mecklenburg County in-center patient census as of December 31, 2016.	149
Project this census forward one year to December 31, 2017, using the Mecklenburg County Five Year AACR.	$1.05 \times 149 = 156.5$
The 5 patients from Gaston and Union Counties and South Carolina are added back in.*	$156.5 + 5 = 161.5$
The 4 in-center patients currently dialyzing at FMC Charlotte who signed letters of support to relocate three dialysis stations to FMC Southwest Charlotte are subtracted.	$161.5 - 4 = 157.5$
Projected patient census for December 31, 2017, date of certification for stations relocating to FMC Southwest Charlotte.	157.5*

*The applicant assumes no growth for patients who do not reside in Mecklenburg County. Further, the applicant assumes the two patients from “Other States” dialyzing at FMC Charlotte as of 12/31/16 to be transient patients and not projected to continue dialysis at the facility in the future. (See page 26 of the application.)

By the end of 2017, FMC Charlotte will have approximately 157 in-center patients dialyzing on 44 stations, which is a utilization rate of 89.25%, or 3.57 patients per station per week [$157 / 44 = 3.57$; $3.57 / 4 = 0.8925$ or 89.25%].

The project does not propose to relocate any existing dialysis stations from the BMA Nations Ford dialysis facility.

The applicant states that it will continue to make dialysis services available to all residents in the service area, stating that the relocation of stations will not affect the ability of underserved groups to obtain needed care at either dialysis facility or a BMA facility closer to where they reside. (See page 27.)

The applicant demonstrates that the needs of the populations presently served at FMC Charlotte will continue to be adequately met following the proposed relocation of dialysis stations, and that access for medically underserved groups will not be negatively impacted by the relocation.

- (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 28, 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 Southwest Charlotte to accommodate existing BMA patients who dialyze at other

BMA facilities but reside in closer proximity to FMC Southwest Charlotte. Maintaining the status quo would not permit BMA to enhance access for existing patients to dialysis services by re-distributing existing dialysis stations within Mecklenburg County.

2. Apply to Relocate Stations from a Different BMA facility in Mecklenburg County- relocating stations from FMC Charlotte will result in a facility need for three stations at FMC Charlotte in the July 2017 Semi-Annual Dialysis Report (SDR) and thus allow BMA to add stations back to FMC Charlotte and thus provide sufficient dialysis capacity for the growing population in Mecklenburg County.
3. Relocate Existing Stations to another BMA facility in Mecklenburg County- This would not have served to improve access to FMC Southwest Charlotte for existing BMA patients who reside in closer proximity to FMC Charlotte than the BMA facility where they are currently dialyzing.

After considering these alternatives to its proposal, the applicant believes the most effective and least costly alternative is to add three stations by relocating existing dialysis stations from FMC Charlotte to ensure adequate access for the patients of FMC Southwest Charlotte.

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 three more stations at FMC Southwest Charlotte. 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 Southwest Charlotte 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 Southwest Charlotte shall develop and operate no more than three additional dialysis stations for a total of 13 certified stations following completion of this project which shall include any home hemodialysis training or isolation stations.**
- 3. Bio-Medical Applications of North Carolina, Inc., d/b/a FMC Southwest Charlotte shall install plumbing and electrical wiring through the walls for three additional dialysis stations for a total of 13 dialysis stations which shall include any home hemodialysis training or isolation stations.**
- 4. Upon certification of the three additional dialysis stations at the FMC Southwest Charlotte facility, Bio-Medical Applications of North Carolina, Inc. shall take the steps necessary to delicense three dialysis stations at its FMC Charlotte facility.**

5. Bio-Medical Applications of North Carolina, Inc., d/b/a FMC Southwest Charlotte 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 relocate three dialysis stations from FMC Charlotte to FMC Southwest Charlotte for a total of 13 dialysis stations upon completion of this project. FMC Southwest Charlotte offers a home hemodialysis and peritoneal program.

Capital and Working Capital Costs

In Section F, page 27, and Form F.1a in Section Q, the applicant projects the capital cost for the proposed project, as summarized in the table below:

Projected Capital Costs	
(RO) water treatment equipment	\$2,250
Equipment/furniture not included above	\$9,000
Total	\$11,250

In Section F, page 33, the applicant states that there are no working capital needs for the proposed project since FMC Southwest Charlotte 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 SOUTHWEST CHARLOTTE REVENUE AND EXPENSES		
	OY 1 CY 2018	OY 2 CY 2019
Total Treatments	6,372	6,669
Gross Revenue	\$27,772,432	\$28,956,868
Deductions from Gross Patient Revenue	(\$25,153,129)	(\$26,222,316)
Net Revenue	\$2,619,303	\$2,734,552
Operating Expenses	(\$1,762,295)	(\$1,821,679)
Net Income	\$857,007	\$912,873

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 relocate three dialysis stations from FMC Charlotte to FMC Southwest Charlotte for a total of 13 dialysis stations upon completion of this project. FMC Southwest Charlotte 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 Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

According to the January 2017 SDR indicates that BMA has eleven dialysis facilities (seven existing and four approved) in Mecklenburg County, as shown below.

**Mecklenburg County Dialysis Facilities
 as of June 30, 2016**

Dialysis Facilities	Owner	# of Patients	Location	# of Certified Stations	# of Approved Stations	Percent Utilization
BMA Beatties Ford	BMA	126	Charlotte	32	11	98.44%
BMA Nations Ford	BMA	112	Charlotte	28	0	100.0%
BMA of East Charlotte	BMA	90	Charlotte	25	0	90.0%
BMA of North Charlotte	BMA	133	Charlotte	36	0	92.36%
BMA West Charlotte	BMA	97	Charlotte	29	-2	83.62%
FMC Charlotte	BMA	150	Charlotte	43	-6	87.21%
FMC Matthews	BMA	91	Matthews	21	0	108.33
FMC of Southwest Charlotte*	BMA	0	Charlotte	0	10	0.00%
FMC Regal Oaks	BMA	0	Charlotte	0	12	0.00%
FKC Southeast Mecklenburg County	BMA	0	Pineville	0	0	0.00%
FMC Aldersgate	BMA	0	Charlotte	0	10	0.00%

Source: January 2017 SDR

*Note: FMC Southwest Charlotte is a new facility which began offering services on 11/23/16.

As shown in the table above, all of BMA's operational dialysis facilities are operating at or above 83% utilization as of June 30, 2016. Therefore, the facilities are well utilized.

In Section C-1, pages 16-18, the applicant demonstrates that FMC Southwest Charlotte will serve a total of 44 in-center patients at the end of OY1 for a utilization rate of 84.5% or 3.38 patients per station per week (44 patients / 13 stations = 3.38 / 4 = 0.845 or 84.5%). The projected utilization of 3.38 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).

Table B: ESRD Dialysis Station Need Determination by Planning Area in the January 2017 SDR shows a surplus of 22 dialysis stations in Mecklenburg County. However, the applicant is not proposing to add any new (or additional) dialysis stations in the Mecklenburg County Planning Area. The applicant is only proposing to relocate three existing dialysis stations from one BMA facility in Charlotte to a different BMA facility in Charlotte, both of which are in Mecklenburg County.

The applicant adequately demonstrates the need to relocate three existing dialysis stations to FMC Southwest Charlotte 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 Mecklenburg 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.

In Section H, page 41, the applicant provides the following table to illustrate current and projected staffing in full time equivalents (FTEs) for FMC Southwest Charlotte. 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	1.50		1.50
Technician (PCT))	4.00		4.00
Clinical Manager	1.00		1.00
Administrator	0.20		0.20
Dietician	0.40		0.40
Social Worker	0.40		0.40
Home Training Nurse	0.75		0.75
Chief Tech	0.20		0.20
Equipment Tech	0.50		0.50
In-Service	0.20		0.20
Clerical	1.00		1.00
Total	10.15	0.00	10.15

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

In Section H, page 43, the applicant provides the projected direct care staff for FMC Southwest Charlotte in OY2 (CY2018).

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	1.50	2,080	3,120	3,744	0.83
Technician (PCT)	4.00	2,080	8,320	3,744	2.22
Home Training RN	0.75	2,080	1,560	3,744	0.42
Total	6.25	2,080	13,000	3,744	3.47

In Section H, page 43, the applicant states dialysis services will be available from 5:00 AM to 5:00 PM, Monday through Saturday for a total of 12 hours per day/ 72 hours per week.

In Section I, page 45, the applicant identifies Dr. Chris Fotiadis as the Medical Director of the facility. In Exhibit I-5, the applicant provides a copy of a letter signed by Dr. Fotiadis of Metrolina Nephrology Associates, PA supporting the project and confirming his commitment to serve as Medical Director. In Section H, page 41, 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 44, 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 of the application. 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

FMC Southwest Charlotte is a newly developed facility that started serving patients on November 23, 2016.

In Section L, page 58, the applicant reports that 80.0% of the patients who received treatments at FMC Southwest Charlotte had some or all of their services paid for by Medicare or Medicaid during the approximate thirty eight days the facility was operational in 2016. The table below shows the historical payment sources of the facility from 11/23/16 to 12/31/16.

FMC Southwest Charlotte*

Payment Source	Percent of Total Patients
Commercial Insurance	16.0%
Medicare	74.0%
Medicaid	2.0%
Medicare/ Commercial	4.0%
Miscellaneous (Incl. VA)	2.0%
Other: Self/Indigent/Charity	2.0%
Total	100.00%

*Note: FMC Southwest Charlotte is a new facility which began offering services on 11/23/16.

On page 58, the applicant also provided the historical payor source data for FMC Charlotte, the facility from which the three dialysis stations are being relocated, which demonstrated that 75.15% of the patients who received treatments at FMC Charlotte during CY2016 had some or all of their services paid for by Medicare or Medicaid.

FMC Charlotte

Payment Source	Percent of Total Patients
Commercial Insurance	21.27%
Medicare	64.77%
Medicaid	5.29%
Medicare/ Commercial	5.09%
Miscellaneous (Incl. VA)	1.47%
Other: Self/Indigent/Charity	2.11%
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
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).

The applicant adequately demonstrates that it currently provides access to medically underserved populations. Therefore, the application is conforming to this criterion.

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

²<http://esrd.ipro.org/wp-content/uploads/2016/11/2015-NW-6-Annual-Report-Final-Draft-with-COR-Changes-Submitted-11-29-2016.pdf>

- (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 56, 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 57, 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 54, 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 55, the applicant projects that 80.0% of all patients in OY2 (CY2018) 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	16.0%
Medicare	74.0%
Medicaid	2.0%
Medicare/ Commercial	4.0%
Miscellaneous (Incl. VA)	2.0%
Other: Self/Indigent/Charity	2.0%
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, pages 56-57, 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 Southwest Charlotte 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 Southwest Charlotte 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 59, the applicant refers to a letter dated May 12, 2017 addressed to Central Piedmont Community College which states “*Fresenius would like to invite you to include the FMC Southwest Charlotte 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 relocate three dialysis stations from FMC Charlotte to FMC Southwest Charlotte for a total of 13 dialysis stations upon completion of this project. FMC Southwest Charlotte 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 Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

According to the January 2017 SDR indicates that BMA has eleven dialysis facilities (seven existing and four approved) in Mecklenburg County, as shown below.

**Mecklenburg County Dialysis Facilities
 as of June 30, 2016**

Dialysis Facilities	Owner	# of Patients	Location	# of Certified Stations	# of Approved Stations	Percent Utilization
BMA Beatties Ford	BMA	126	Charlotte	32	11	98.44%
BMA Nations Ford	BMA	112	Charlotte	28	0	100.0%
BMA of East Charlotte	BMA	90	Charlotte	25	0	90.0%
BMA of North Charlotte	BMA	133	Charlotte	36	0	92.36%
BMA West Charlotte	BMA	97	Charlotte	29	-2	83.62%
FMC Charlotte	BMA	150	Charlotte	43	-6	87.21%
FMC Matthews	BMA	91	Matthews	21	0	108.33%
FMC of Southwest Charlotte	BMA	0	Charlotte	0	10	0.00%
FMC Regal Oaks	BMA	0	Charlotte	0	12	0.00%
FKC Southeast Mecklenburg County	BMA	0	Pineville	0	0	0.00%
FMC Aldersgate	BMA	0	Charlotte	0	10	0.00%

Source: January 2017 SDR

As shown in the table above, all of BMA’s operational dialysis facilities are operating at or above 83% utilization as of June 30, 2016. Therefore, the facilities are well utilized.

The applicant proposes to relocate three existing dialysis stations from one BMA facility in Charlotte to a different BMA facility in Charlotte, both of which are in Mecklenburg County.

In Section N, page 60, the applicant discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services and states:

“BMA does not expect this proposal to have effect on the competitive climate in Mecklenburg County. BMA does not project to serve dialysis patients currently being served by another provider. The projected patient population for the FMC Southwest Charlotte facility begins with patients currently served by BMA. The transfer of patients currently dialyzing with BMA, and a growth of that patient population consistent with the Mecklenburg County five year average annual change rate of 5.0% 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 Southwest Charlotte will continue to provide quality dialysis services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- The applicant adequately demonstrates that FMC Southwest Charlotte will continue to provide 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, Section O, pages 62-66 and Exhibit O-1, the applicant discusses the methods it uses to ensure and maintain quality. In Exhibit O-2, the applicant provides a document indicating that a survey of FMC Southwest Charlotte was completed on November 16, 2016 and “no deficiencies were cited.”

In Section O, pages 63-64, 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
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 16-18, the applicant demonstrates that FMC Southwest Charlotte will serve a total of 44 in-center patients at the end of OY1 (CY2018) for a utilization rate of 84.5% or 3.38 patients per station per week ($44 \text{ patients} / 13 \text{ stations} = 3.38 / 4 = 0.845$ or 84.5%). 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 16-18, the applicant provides the assumptions and methodology used to project utilization of FMC Southwest Charlotte. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.