

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming  
CA = Conditional  
NC = Nonconforming  
NA = Not Applicable

Decision Date: May 7, 2015

Findings Date: May 7, 2015

Project Analyst: Celia C. Inman

Team Leader: Lisa Pittman

Project ID #: F-11012-15

Facility: FMC Matthews

FID #: 080137

County: Mecklenburg

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

Project: Add no more than 8 dialysis stations for a total of no more than 21 stations upon completion of this project and Project ID #F-10369-15 (relocate 8 stations to FMC Regal Oaks)

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a FMC Matthews (“the applicant”) proposes to add eight dialysis stations for a total of 21 stations upon completion of this project and Project ID #F-10369-15 (relocate eight stations from FMC Matthews to FMC Regal Oaks). FMC Matthews is an existing facility located at 910 Park Center Drive, Matthews in Mecklenburg County.

#### **Need Determination**

The 2015 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations.

According to the January 2015 Semiannual Dialysis Report (SDR), the county need methodology indicates there is no need for additional stations in Mecklenburg County. However, the applicant is eligible to apply for additional stations based on the facility need methodology, because the utilization rate reported for FMC Matthews in the January 2015 SDR is 4.0 patients per station. This utilization rate was calculated based on 84 in-center dialysis patients and 21 certified dialysis stations as of June 30, 2014 (84 patients / 21 stations = 4.0 patients per station).

Application of the facility need methodology indicates a potential need for eight additional stations at FMC Matthews, as illustrated in the following table.

<b>April 1 Review – January SDR</b>		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/14		100.0%
Certified Stations		21
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>21</b>
In-Center Patients as of 6/30/14 (SDR2)		84
In-Center Patients as of 12/31/13 (SDR1)		75
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	9
	Multiply the difference by 2 for the projected net in-center change	18
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/13	0.24
(ii)	Divide the result of step (i) by 12	0.02
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/14 until 12/31/14)	0.12
(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	94.08
(v)	Divide the result of step (iv) by 3.2 patients per station	29.40
	and subtract the number of certified and pending stations as recorded in SDR2 to determine the number of stations needed (21 stations)	<b>8</b>

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

## **Policies**

There is one policy in the 2015 SMFP that is applicable to this review, *POLICY GEN-3: BASIC PRINCIPLES*. This policy, located on page 38 of the 2015 SMFP, states:

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

**Promote Safety and Quality** - The applicant describes how it believes the proposed project would promote safety and quality in Section I, pages 4-7, Section II, pages 19-20, Section V, page 42, Section XI.6(g), page 68, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

**Promote Equitable Access** - The applicant describes how it believes the proposed project would promote equitable access in Section II, pages 20-21, Section III, pages 33-35, Section V, page 42, Section VI, pages 43-47, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

**Maximize Healthcare Value** - The applicant describes how it believes the proposed project would maximize healthcare value in Section II, pages 21-22, Section III, pages 34-35, Section V, page 42, Section VIII, pages 52-53, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

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

## **Conclusion**

In summary, the applicant adequately demonstrates that the application is consistent with the facility need determination in the January 2015 SDR and Policy GEN-3. Therefore, the application is conforming to this criterion.

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

C

The applicant proposes to add eight dialysis stations to the existing facility in Matthews for a total of 21 stations upon completion of this project and Project ID #F-10369-15 (relocate eight from FMC Matthews to FMC Regal Oaks).

**Population to be Served**

In Section IV.1, page 36, the applicant identifies the population of in-center and home dialysis patients served at FMC Matthews, as of December 31, 2014, as shown in the table below:

**FMC Matthews Patient Origin**

County of Residence	In-Center Patients	Home Patients
Mecklenburg	85	0
Other - Union	11	0
<b>Total</b>	<b>96</b>	<b>0</b>

FMC Matthews provides in-center dialysis treatment only as shown in the table above. BMA patients in need of home dialysis services are referred to another dialysis facility in Mecklenburg County that provides home dialysis training.

In Section III.7, page 33, the applicant provides a table showing the projected patient origin of the patients to be served at FMC Matthews for the first two years of operation following completion of the project and Project ID #F-10369-15, as shown below.

**Projected FMC Matthews Patient Origin**

County	Operating Year One	Operating Year Two	County Patients as a Percent of Total	
	In-Center	In-Center	Year 1	Year 2
Mecklenburg	84.9	90.9	88.5%	89.2%
Union	11.0	11.0	11.5%	10.8%
<b>Total</b>	<b>95.9</b>	<b>101.9</b>	<b>100.0%</b>	<b>100.0%</b>

The applicant adequately identifies the population FMC Matthews proposes to serve.

### **Analysis of Need**

BMA proposes to add eight dialysis stations to the FMC Matthews facility following the relocation of eight dialysis stations from FMC Matthews to the proposed FMC Regal Oaks facility, which is projected to be certified as of June 30, 2016. BMA projects this project to be completed simultaneously with the FMC Regal Oaks facility. In Section III.7, pages 31-33, the applicant provides the assumptions and methodology it uses to determine the need for the additional dialysis stations at FMC Matthews. The assumptions and methodology are summarized below:

- The applicant assumes that the patient population of FMC Matthews residing within Mecklenburg County will continue to increase at the 7.1% Mecklenburg County Five Year Average Annual Change Rate as reported in the January 2015 SDR.
- In Project ID #F-10369-15, the applicant projects 15 patients will transfer their care to FMC Regal Oaks along with the relocation of the eight dialysis stations. Thus, in this application, the applicant will subtract 15 Mecklenburg County patients as of June 30, 2016.
- The applicant assumes that those FMC Matthews patients residing outside Mecklenburg County will continue to dialyze at FMC Matthews as a function of patient choice; however, the applicant does not project an increase in these patient numbers.
- The project is scheduled to be completed June 30, 2016. Operating Year One is July 1, 2016 – June 30, 2017. Operating Year Two is July 1, 2017 – June 30, 2018.

#### *Projected Utilization*

In Section III, page 33, the applicant provides the calculations used to arrive at the projected patient census for Operating Year One, as of June 30, 2017 and Operating Year Two, as of June 30, 2018, as shown below.

<i>FMC Matthews</i>	<i>In-Center Dialysis</i>
BMA begins with the 85 in-center Mecklenburg County dialysis patients at FMC Matthews as of December 31, 2014.	85
BMA projects growth of the Mecklenburg County patients by the Mecklenburg County Five Year Average Annual Change Rate for one year to June 30, 2015.	$(85 \times .071) + 85 = 91.0$
BMA projects this census forward for 6 months to June 30, 2016, projected certification date of this project and Project ID #F-10369-15.	$(91.0 \times .071/12 \times 6) + 91.0 = 94.3$
BMA subtracts 15 patients expected to transfer their care to FMC Regal Oaks facility upon certification on June 30, 2016	$94 - 15 = 79$
BMA adds the 11 Union County patients for the projected beginning patient census for FMC Matthews on June 30, 2016	$79 + 11 = 90$
BMA projects growth of the Mecklenburg County patients by the Mecklenburg County Five Year Average Annual Change Rate for one year to June 30, 2017.	$(79.3 \times .071) + 79.3 = 84.9$
BMA adds the 11 Union County patients. This is the projected ending patient census for Operating Year One.	$84 + 11 = 95$
BMA again projects the growth of the Mecklenburg County patient census by the Mecklenburg County Five Year Average Annual Change Rate for one year to June 30, 2018.	$(84.9 \times .071) + 84.9 = 90.9$
BMA adds the 11 Union County patients. This is the projected ending patient census for Operating Year Two.	$90 + 11 = 101.9^*$

\*applicant rounded down

As shown in the previous table, at the end of Operating Year One, FMC Matthews is projecting an in-center patient census of 95 patients for a utilization rate of 113% or 4.52 patients per station ( $95 \text{ patients} / 21 \text{ stations} = 4.52 / 4 = 1.13$ ). At the end of Operating Year Two, the applicant is projecting an in-center patient census of 101.9, for a utilization rate of 120% or 4.8 patients per station ( $101 \text{ patients} / 21 \text{ stations} = 4.80 / 4 = 1.20$ ). The projected utilization of 4.52 patients per station per week for Operating Year One satisfies the 3.2 in-center patients per station threshold as required by 10A NCAC 14C .2203(b). The applicant states that exceeding 100% of capacity is accomplished by operating evening and nocturnal dialysis shifts three days per week.

The applicant adequately demonstrates that projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

**Access**

In Section VI.1, page 43, the applicant states:

*“It is clear that BMA plans to provide services to historically underserved populations. 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.”*

On page 43, the applicant states that the patient population of the FMC Matthews facility is expected to be comprised of the following, based upon the facility’s historical payor mix:

Facility	Medicaid/Low Income	Elderly(65+)	Medicare	Women	Racial Minorities
FMC Matthews	5.2%	61.5%	62.0%	51.0%	50.0%

The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 62.0% of the facility treatment reimbursement is from Medicare.

On page 44, the applicant projects that approximately 87.35% of its in-center patients will be covered by some form of Medicare or Medicaid. The applicant adequately demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services.

**Conclusion**

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

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

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

CA

In Section III.9, pages 34-35, the applicant discusses the alternatives considered prior to submitting this application, which include:

- 1) Submitting an application for fewer stations. The applicant did not consider this alternative as viable because FMC Matthews, with an addition of eight stations, is projected to exceed 100% utilization, even after the transfer of 15 patients to the proposed FMC Regal Oaks facility.
- 2) Relocation of stations from another BMA facility in Mecklenburg County to the FMC Matthews facility. However, the applicant states that each of the BMA facilities in Mecklenburg County are highly utilized; in addition, BMA is in the process of adding stations to other Mecklenburg facilities and developing new Mecklenburg facilities. Thus, the applicant determined that the relocation of stations to FMC Matthews alternative was not viable at this time.
- 3) Maintain the Status Quo - the applicant states that failure to develop the additional stations will eventually remove choice from the patient.

After considering the above alternatives, the applicant states that the alternative proposed in this application, add eight stations to the FMC Matthews facility, is the most effective alternative.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that this proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

- 1. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Matthews shall materially comply with all representations made in the certificate of need application.**
- 2. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Matthews shall develop and operate no more than eight additional dialysis stations for a total of no more than 21 certified dialysis stations upon completion of this project and Project ID #F-10369-15 (relocate eight dialysis stations to FMC Regal Oaks), which shall include any home hemodialysis and isolation stations.**
- 3. 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 Agency in writing prior to issuance of the certificate of need.**

- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

In Section VIII, pages 52-53, the applicant states that BMA will not incur any capital costs associated with the proposed project.

In Section IX, page 55, the applicant states that as an existing facility, no start up or initial operating expenses are associated with the proposed project.

Exhibit 24 contains a March 16, 2015 letter from the Vice President of Fresenius Medical Care Holdings, Inc., which states,

*“BMA is submitting a Certificate of Need Application to add eight dialysis stations to its FMC Matthews facility, following relocation of eight dialysis stations to the new FMC Regal Oaks facility (CON Project ID #F-10369-15). FMC Matthews will have a total of 21 dialysis stations upon completion of this project. The project does not require any capital expenditure on behalf of BMA.*

*As Vice President, I am authorized and do hereby authorize the addition of eight dialysis stations.”*

In Section VIII.7, page 53, the applicant refers to Exhibit 4 for a copy of the most recent audited Fresenius Medical Care Holdings, Inc. Consolidated Balance Sheets for 2012 and 2013 along with a copy of the Auditor’s letter. As of December 31, 2013, FMC Holdings, Inc. and Subsidiaries had \$275,719,000 in cash and cash equivalents with \$16,597,314,000 in total assets and \$8,521,824,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of funds for unexpected capital and working capital needs.

In Section X.1, page 56, the applicant provides its allowable charges per treatment for each payment source, as illustrated below:

**Allowable Charge Per Treatment**

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

The applicant provides the following explanations for charges and reimbursement on pages 56-58,

*“The commercial charges above do not reflect actual reimbursement rates, and should not be taken as absolute. It is industry standard for providers to have contractual relationships with various payors, resulting in less reimbursement than the stated charge.*

...

*BMA also notes that Medicare began the “Bundling” reimbursement program in 2010. The Bundling program provides one basic fee for the dialysis treatment; this fee includes all ancillary services which were previously billed separately. As a consequence of this, the basic rate for Medicare reimbursement has been approximately \$240 per treatment. Medicare will provide additional reimbursement for some co-morbid conditions. BMA has reflected a Medicare rate of \$239 in the above table.”*

The applicant projects revenues in Section X.2-4, pages 57-63, and operating expenses in Section X.4, page 62, as summarized in the table below:

<b>FMC Matthews</b>	<b>Operating Year One 7/1/16-6/30/17</b>	<b>Operating Year Two 7/1/17-6/30/18</b>
Gross Patient Revenue	\$ 5,923,051	\$ 6,259,445
Contractual Allowances	\$ 905,422	\$ 954,100
Total Net Revenue	\$ 5,017,629	\$ 5,305,345
Total Operating Expenses*	\$ 4,147,906	\$ 4,333,193
<b>Net Profit</b>	<b>\$ 869,723</b>	<b>\$ 972,152</b>

\*Includes bad debts/charity and income taxes

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. See Section X.3, pages 58-59 for the applicant’s assumptions,

including number of treatments (3 treatments/week, 52 weeks/year, and 6.5% missed treatments) for in-center patients. The applicant's projections of treatments and revenues are reasonable based on the number of in-center patients projected for the first two operating years. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

In Section VII.1, page 48, the applicant provides projected staffing and salaries. The tables in Sections X.4 and X.5, pages 62-63, show budgeted operating costs adequate to cover the projected staffing.

In summary, the applicant adequately demonstrates the availability of sufficient funds for capital and working capital needs of the project. The applicant also adequately demonstrates that the financial feasibility of the project is based on reasonable projections of revenues and operating costs. 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

The applicant proposes to add eight dialysis stations to the existing FMC Matthews facility for a total of 21 stations upon completion of this project and Project ID #F-10369-15 (relocate eight stations from FMC Matthews to FMC Regal Oaks). The January 2015 SDR indicates there are 17 dialysis facilities in Mecklenburg County, as follows:

**Mecklenburg County Dialysis Facilities**

<b>Dialysis Facility</b>	<b>Certified Stations 6/30/14</b>	<b>% Utilization</b>	<b>Patients Per Station</b>
BMA Beatties Ford (BMA)	32	96.09%	3.84
BMA Nations Ford (BMA)	24	113.54%	4.54
BMA East Charlotte (BMA)	24	69.79%	2.79
BMA North Charlotte (BMA)	28	110.71%	4.42
BMA West Charlotte (BMA)	29	70.69%	2.82
Carolinas Medical Center (CMC)	9	47.22%	1.88
Charlotte Dialysis (DaVita)	35	80.00%	3.20
Charlotte East Dialysis (DaVita)	24	84.38%	3.37
DSI Charlotte Latrobe (RAI)	24	67.71%	2.70
DSI Glenwater (RAI)	42	73.21%	2.92
FMC Charlotte (BMA)	40	86.88%	3.47
FMC Matthews (BMA)	21	100.00%	4.00
FMC Southwest Charlotte (BMA)*	0	0.00%	0.00
Huntersville Dialysis (DaVita)*	0	0.00%	0.00
Mint Hill Dialysis (DaVita)	10	87.50%	3.50
North Charlotte Dialysis (DaVita)	35	88.57%	3.54
South Charlotte Dialysis (DaVita)	20	73.75%	2.95

Source: January 2015 SDR, Table A.

\*New Site, no data reported

The applicant operates eight of the 17 dialysis facilities in Mecklenburg County. DaVita, RAI Care Centers of North Carolina II, LLC (RAI) and Carolinas Medical Center (CMC) are the other providers of dialysis services in Mecklenburg County, as shown in the table above. Nine of the seventeen Mecklenburg County dialysis facilities are operating above 80% utilization (3.2 patients per station), two of the seventeen facilities are operating between 70% and 80% utilization, three of the seventeen facilities are operating below 70% utilization and two of the seventeen facilities were not operational at the time of the report.

As shown in the Mecklenburg County Dialysis Facility Data table above, FMC Matthews was operating at 100% of capacity, as of June 30, 2014. The applicant provides data demonstrating that, as of December 31, 2014, FMC Matthews was operating at 114% of capacity (operating a third shift).

The applicant is proposing to add eight additional stations at FMC Matthews, following the relocation of eight stations from FMC Matthews to FMC Regal Oaks (Project ID #F-10369-15). In Section III.7, pages 31-32, the applicant discusses the timing and coordination of this project and Project ID #10369-15 (relocate eight stations from FMC Matthews to FMC Regal Oaks) with this project being complete on June 30, 2016, simultaneously with the FMC Regal Oaks certification of the eight relocated stations. The applicant demonstrates that FMC Matthews will serve a total of 95 in-center patients on 21 stations at the end of the first operating year, which is 4.52 patients per station per week, or a utilization rate of 113% ( $95/21 = 4.52$ ;  $4.52/4 = 1.13$ ). In Section III.7, page

33, the applicant states that it can accomplish exceeding 100% of capacity by operating evening and nocturnal dialysis shifts three days a week.

The applicant adequately demonstrates the need to add eight additional stations to its existing facility based on the facility need methodology and the number of in-center patients it proposes to serve. The discussions regarding analysis of need and competition found in Criteria (3) and (18a), respectively, are incorporated herein by reference.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities in 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.

C

The following table illustrates the current and projected staffing for FMC Matthews, as provided by the applicant in Section VII.1, page 48. The table provided by the applicant erroneously lists the RN positions at the top and bottom of the list; however, the sum total provided on the applicant's table is correct as calculated by the Project Analyst.

**Number of Full Time Equivalentents**

<b>Position</b>	<b>Current FTEs</b>	<b>Projected FTEs</b>
RN	4.00	6.00
Technician	13.00	15.00
Clinical Manager	1.00	1.00
Medical Director*		
Administration – FMC Director of Operations	0.25	0.25
Dietitian	1.00	1.00
Social Worker	1.00	1.00
Chief Technician	0.10	0.10
Equipment Technician	0.65	0.65
In-Service	0.50	0.50
Clerical	1.00	1.00
<b>Total</b>	<b>22.50</b>	<b>26.50</b>

\*The Medical Director is a contract position, not an FTE of the facility.

In Section VII.10, page 51, the applicant provides the number of direct care staff for each shift offered at FMC Matthews.

	Shift Times	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Morning	7:00 am-12:00 pm	9	9	9	9	9	9
Afternoon	12:00 pm-5:00 pm	9	9	9	9	9	9
Evening	5:00 pm-10:00 pm	6	0	6	0	6	0
Nocturnal*	9:00 pm-5:00 am	6	0	6	0	6	0

\*FMC Matthews operates a nocturnal dialysis shift three days a week.

In Section V.4, page 41, the applicant states that Dr. Carl Fisher will serve as the Medical Director for FMC Matthews. In Exhibit 21, the applicant provides a letter dated March 5, 2015 signed by Dr. Fisher of Metrolina Nephrology Associates in support of the proposed project and confirming his commitment to continue to serve as Medical Director. In Section VII.4, page 49, the applicant states, “*BMA anticipates no difficulties in filling staff positions.*” In Section V.4(d), page 41, the applicant lists 31 nephrologists who will be available to provide medical coverage for dialysis patients at FMC Matthews. In Section VII, page 50, the applicant states, “*One or more of the 31 physicians of MNA have hospital privileges at one or more of the following hospitals: Carolinas Medical Center, CMC-Northeast, CaroMont Regional Medical Center, CMC-Mercy and Presbyterian Hospital-Charlotte.*”

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 V.1, page 38, the applicant lists the providers of the necessary ancillary and support services to be provided at FMC Matthews. The applicant discusses coordination with the existing health care system on pages 39-41. Exhibit 21 contains documentation of nephrology services. Exhibits 25 and 26 contain documentation of a Patient Transfer Agreement and a Transplantation Services Agreement, respectively, with Carolinas Medical Center. The information in Section V and Exhibits 21, 25 and 26 is reasonable and credible.

The applicant adequately demonstrates that the necessary ancillary and support services will continue to be available and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

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

NA

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

NA

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

NA

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

C

In Section VI.1(a), page 43, the applicant states that Fresenius Medical Care Holdings, Inc., parent company to BMA, currently operates 102 dialysis facilities in 42 North Carolina counties (including affiliations with Renal Research Institute facilities). The applicant further states, *“Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.”* The patient population of the FMC Matthews facility is expected to be comprised of the following:

Facility	Medicaid/Low Income	Elderly(65+)	Medicare	Women	Racial Minorities
FMC Matthews	5.2%	61.5%	62.0%	51.0%	50.0%

Note: The Medicare percentage represents patients receiving some type of Medicare benefit. This is not to say that 62% of the facility treatment reimbursement is from Medicare.

On pages 43-44, the applicant further states:

*“The historical performance does change as new patients are admitted. Commercial insurance for patients generally covers the patient for a period of 30 months from the beginning of treatment; thereafter, Medicare provides coverage for the patient. The commercial insurance population is therefore constantly changing. In addition, not every patient beginning dialysis has commercial insurance. Thus, the payor mix should be considered dynamic and not fixed.”*

In Section VI.1(b), page 44, the applicant reports that as of December 30, 2014, 87.35% of the patients who were receiving treatments at FMC Matthews had some or all of their services paid for by Medicare or Medicaid in the past year. The following table illustrates the historical payment source for those facilities.

**HISTORICAL PAYOR MIX**

<b>SOURCE OF PAYMENT</b>	<b>FMC Matthews</b>
Commercial Insurance	9.20%
Medicare	64.05%
Medicaid	4.02%
Medicare / Commercial	19.28%
VA	0.94%
Self Pay / Indigent	2.51%
<b>Total</b>	<b>100.00%</b>

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The



following table illustrates those percentages for Mecklenburg County and statewide.

	<b>2010 Total # of Medicaid Eligibles as % of Total Population *</b>	<b>2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *</b>	<b>2009 % Uninsured (Estimate by Cecil G. Sheps Center) *</b>
Mecklenburg County	14.7%	5.1%	20.1%
Statewide	16.5%	6.7%	19.7%

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

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by dialysis facilities. In fact, in 2013 only 6.6% of all newly-diagnosed ESRD patients in North Carolina were under the age of 35, according to the ESRD Network 6 2013 Annual Report. (*ESRD Network 6 2013 Annual Report/Data Table 1: ESRD Incidence – One Year Statistics as of 1/1/2013 – 12/31/2013, page 99.*)<sup>1</sup>

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

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

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

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

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

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

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

The 2013 USRDS Annual Data Report (p. 332) provides 2011 ESRD spending by payor, as follows:

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

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

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

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

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

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

C

In Section VI.1(f), page 45, the applicant states,

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

In Section VI.6, page 46, the applicant states, *“There have been no Civil Rights complaints lodged against any BMA North Carolina facilities in the past five years.”*

The application is conforming to this criterion.

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

C

In Section VI.1(d), page 45, the applicant states,

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

On page 44, the applicant reports that it expects more than 87% of the in-center patients who receive treatments at FMC Matthews to have all or part of their services paid for by Medicare or Medicaid, as indicated below.

**Projected Payor Mix**

<b>Payor Source</b>	<b>FMC Matthews</b>
Commercial Insurance	9.20%
Medicare	64.05%
Medicaid	4.02%
Medicare / Commercial	19.28%
VA	0.94%
Self Pay / Indigent	2.51%
<b>TOTAL</b>	<b>100.00%</b>

The applicant projects no change from the current payor mix for in-center dialysis services. The applicant demonstrates that medically underserved populations will have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section VI.5, page 46, 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 Matthews will have an open policy, which means that any Nephrologist may apply to admit patients at the facility. The attending physicians receive referrals from other physicians or Nephrologists or hospital emergency rooms.*

*Patients cannot self-refer for dialysis and dialysis treatment does require orders from an attending physician with staff privileges at the facility. 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 it will offer a range of means by which patients will have access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section V.3, pages 39-40, the applicant states:

*“Exhibit 19 contains a letter to Central Piedmont Community College encouraging the school to include the FMC Matthews facility in their clinical rotations for nursing students.*

...

*All health related education and training programs are welcomed to visit the facility, receive instruction and observe the operation of the unit while patients are receiving treatment. This experience enhances the clinical experience of the students enrolled in these programs enabling them to learn about the disease, prognosis and treatment for the patient with end stage renal disease.”*

Exhibit 19 contains a copy of a letter from Fresenius Medical Care to the Director of Health & Human Services at Central Piedmont Community College inviting the college to include FMC Matthews in the clinical rotation for its nursing students. The information provided in Section V.3 and referenced exhibits is reasonable and credible and supports a finding of conformity with 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

The applicant proposes to add eight dialysis stations for a total of 21 stations upon completion of this project and Project ID #F-10369-15 (relocate eight stations from FMC Matthews to FMC Regal Oaks). According to the January 2015 SDR, there are 17 dialysis facilities in Mecklenburg County, listed as follows:

**Mecklenburg County Dialysis Facilities**

<b>Dialysis Facility</b>	<b>Certified Stations 6/30/14</b>	<b>% Utilization</b>
BMA Beatties Ford (BMA)	32	96.09%
BMA Nations Ford (BMA)	24	113.54%
BMA East Charlotte (BMA)	24	69.79%
BMA North Charlotte (BMA)	28	110.71%
BMA West Charlotte (BMA)	29	70.69%
Carolinas Medical Center (CMC)	9	47.22%
Charlotte Dialysis (DaVita)	35	80.00%
Charlotte East Dialysis (DaVita)	24	84.38%
DSI Charlotte Latrobe (RAI)	24	67.71%
DSI Glenwater (RAI)	42	73.21%
FMC Charlotte (BMA)	40	86.88%
FMC Matthews (BMA)	21	100.00%
FMC Southwest Charlotte (BMA)*	0	0.00%
Huntersville Dialysis (DaVita)*	0	0.00%
Mint Hill Dialysis (DaVita)	10	87.50%
North Charlotte Dialysis (DaVita)	35	88.57%
South Charlotte Dialysis (DaVita)	20	73.75%

Source: January 2015 SDR, Table A.

\*New Site, no data reported

As the table above illustrates, the eight BMA Mecklenburg facilities, on average, are highly utilized. FMC Matthews is operating at 100% of capacity.

In Section V.7, page 42, the applicant discusses how any enhanced competition in the service area will promote cost-effectiveness, quality and access to the proposed services. The applicant states,

*“BMA does not expect this proposal to have effect on the competitive climate in Mecklenburg County.*

...

*BMA seeks the opportunity to continue providing dialysis care and treatment to the patients of the area who choose dialysis at a BMA facility.*

...

*BMA facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid. The majority of our patients rely upon Medicare and Medicaid to cover the expense of their treatments.*

...

*The facility must capitalize upon every opportunity for efficiency.*

*BMA facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients. Every effort is made to (a) ensure that the applicant thoroughly plans for the success of a facility prior to the application, and, (b) that once the project is completed, all staff members work toward the clinical and financial success of the facility. This facility is no different.*

*This proposal will certainly not adversely affect quality, but rather, enhance the quality of the ESRD patients' lives."*

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

The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that any enhanced competition in the service area includes a positive impact on 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 a cost-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 BMA will continue to provide quality services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- The applicant demonstrates BMA will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (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

According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, FMC Matthews has operated in compliance with all Medicare Conditions of Participation within the 18 months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The application is conforming to all applicable criteria, as discussed below.

**SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES**

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

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

*.2202(a)(1) Utilization rates;*

- C- In Section II.1, page 10, and Exhibit 5 (copy of the January 2015 SDR, Tables A and B), the applicant provides the utilization rates for FMC Matthews. As of June 30, 2014, FMC Matthews had a utilization rate of 100% with 84 in-center patients dialyzing on 21 stations ( $84 / 21 = 4.0$ ;  $4.0 / 4 = 1.0$ )

*.2202(a)(2) Mortality rates;*

- C- In Section II.1, page 10, the applicant reports 2012, 2013 and 2014 facility mortality rates for FMC Matthews, as 11.3%, 11.9% and 9.4%, respectively.



.2202(a)(3) *The number of patients that are home-trained and the number of patients on home dialysis;*

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

.2202(a)(4) *The number of transplants performed or referred;*

-C- In Section II.1, page 10, the applicant reports that FMC Matthews referred 12 patients for transplant evaluation in 2014, and two patients received transplants in 2014.

.2202(a)(5) *The number of patients currently on the transplant waiting list;*

-C- In Section II.1, page 10, the applicant states that FMC Matthews has 12 patients on the transplant waiting list.

.2202(a)(6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*

-C- In Section II.1, page 11, the applicant reports FMC Matthews had a total of 39 hospital admissions in 2014; 18% were dialysis related and 82% were non-dialysis related.

.2202(a)(7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during the last calendar year.*

-C- In Section II.1, page 11, the applicant reports that FMC Matthews had no Hepatitis B conversions in 2013 or 2014.

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

.2202(b)(1) *For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100 (Replaced with 42 CFR Part 494).*

-NA- The applicant does not propose a new facility. FMC Matthews is an existing facility.

- .2202(b)(2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*
- (A) *timeframe for initial assessment and evaluation of patients for transplantation,*
  - (B) *composition of the assessment/evaluation team at the transplant center,*
  - (C) *method for periodic re-evaluation,*
  - (D) *criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and,*
  - (E) *Signatures of the duly authorized persons representing the facilities and the agency providing the services.*

-NA- The applicant does not propose a new facility. FMC Matthews is an existing facility.

- .2202(b)(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*

-NA- The applicant does not propose a new or replacement facility. FMC Matthews is an existing facility.

- .2202(b)(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*

-C- Exhibit 12 contains excerpts from Fresenius' Clinical Services Integrated Policy and Procedure Manual Volume II which includes Guidelines for Use of Emergency Generators Policy in the event of a power outage.

- .2202(b)(5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*

-NA- The applicant does not propose a new facility. FMC Matthews is an existing facility.

- .2202(b)(6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*

-C- The applicant states, in Section II, page 12, that BMA, its parent company, "will provide all services approved by the Certificate of Need in conformity with applicable laws and regulations." See also Sections I, pages 4-7, VII.2, page 49, and Exhibits 12 and 13.

.2202(b)(7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*

-C- In Section II.1, page 13, the applicant provides FMC Matthews’ projected in-center patient origin by county, based on the facility’s existing patient origin.

County	Operating Year One	Operating Year Two	County Patients as a Percent of Total	
			Year One	Year Two
Mecklenburg	84.9	90.9	88.5%	89.2%
Union	11.0	11.0	11.5%	10.8%
<b>Total</b>	<b>95.9</b>	<b>101.9</b>	<b>100.0%</b>	<b>100.0%</b>

The applicant’s assumptions and methodology for its projections are provided on pages 12-13 of the application. The discussion regarding population to be served found in Criterion (3) is incorporated herein by reference.

.2202(b)(8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*

-NA- The applicant does not propose a new facility. FMC Matthews is an existing facility.

.2202(b)(9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement for such services.*

-C- In Section II.1, page 14, the applicant states, “BMA will admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.”

**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 does not propose a new facility. FMC Matthews is an existing facility.

.2203(b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of*

*the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*

- C- In Section II.1, page 15, the applicant projects that it will serve a total of 95 in-center patients on 21 stations at the end of the first operating year, which is 3.52 patients per station per week, or a utilization rate of 113% ( $95 / 21 = 4.52$ ;  $4.52 / 4 = 1.13$ ). The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

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

- C- In Section II.1, pages 12-13, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

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

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

*.2204(1) Diagnostic and evaluation services;*

- C- The applicant states, in Section II, page 16, and Section V, page 38, that diagnostic and evaluation services will be referred to Carolinas Medical Center.

*.2204(2) Maintenance dialysis;*

- C- The applicant states, in Section II, page 16, and Section V, page 38, that the facility will provide in-center maintenance dialysis.

*.2204(3) Accessible self-care training;*

- C- In Section II, page 16, and Section V, page 38, the applicant states that FMC Matthews patients who are candidates for self-care will be referred to the BMA Charlotte home training department for self-care training. In addition, on page 16, the applicant states, “*Upon completion of the training the patient will continue dialysis at FMC Matthews, relying upon self-care, and monitored by the staff of the facility.*”

*.2204(4) Accessible follow-up program for support of patients dialyzing at home;*

- C- The applicant states, in Section II, page 16, that FMC Matthews patients who are candidates for home dialysis will be referred to the BMA Charlotte home training department.

*.2204(5) X-ray services;*

- C- The applicant states, in Section II, page 16 and Section V, page 38, that x-ray services will be provided by Carolinas Medical Center.

*.2204(6) Laboratory services;*

- C- Laboratory services will be provided on-site by the applicant through a contract with Spectra Labs, as stated by the applicant in Section II, page 16, and Section V, page 38. Exhibit 15 contains documentation of a current Laboratory Services Agreement between FMC Matthews and Spectra Laboratories.

*.2204(7) Blood bank services;*

- C- The applicant states, in Section II, page 16, and Section V, page 38, that blood bank services will be provided by Carolinas Medical Center.

*.2204(8) Emergency care;*

- C- The applicant states, in Section II, page 16, and Section V, page 38, that facility staff provide emergency care on site until emergency responders arrive and that a fully stocked 'crash cart' is available for use at the facility. Patients in need of emergency care at a hospital are transported via emergency services.

*.2204(9) Acute dialysis in an acute care setting;*

- C- The applicant states, in Section II, page 16, and Section V, page 38, that acute dialysis in an acute care setting will be provided by Carolinas Medical Center.

*.2204(10) Vascular surgery for dialysis treatment patients;*

- C- The applicant states, in Section II, page 17, that patients needing vascular surgery will be referred to Metrolina Nephrology Associates (MNA) Access Center, Piedmont Surgical or Sanger Heart and Vascular Clinic. In Section V, page 38, the applicant lists Carolinas Medical Center, Sanger Heart and Vascular, and MNA Vascular Access Center as providing vascular surgery services.

*.2204(11) Transplantation services;*

- C- In Section II, page 17, and Section V, page 38, the applicant states that candidates for transplantation services will be referred to Carolinas Medical Center. Exhibit 26 contains a copy of a Transplantation Agreement between the applicant and Carolinas Medical Center.

*.2204(12) Vocational rehabilitation counseling and services; and*

- C- Vocational rehabilitation counseling and services will be provided by the Division of Vocational Rehabilitation of Mecklenburg County, as stated by the applicant in Section II, page 17, and Section V, page 38.

*.2204(13) Transportation*

- C- The applicant states, in Section II, page 17, and Section V, page 38, that transportation services will be provided by Charlotte Area Transportation (CATS), A-1 Wheelchair Transport and area taxi services.

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

*.2205(a) To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R. Section 405.2100 (Replaced with 42 CFR Part 494).*

- C- In Section VII.1, page 48, the applicant provides a current and proposed staffing chart. In Section VII.2, page 49, the applicant states the proposed facility will comply with all staffing requirements as stated in 42 C.F.R. Part 494 (formerly 42 C.F.R., Section 405.2100). The discussion regarding proposed staffing found in Criterion (7) is incorporated herein by reference.

*.2205(b) To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.*

- C- In Sections II, page 18 and VII.5, page 49, the applicant discusses the required training for staff and states that training at BMA facilities is continually updated, as needed, by the In-Service Coordinator and Director of Nursing. Exhibit 9 contains an outline of the training program and Exhibit 10 contains an outline of continuing education programs.