ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

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

Decision Date: December 19, 2016
Findings Date: December 19, 2016

Project Analyst: Gloria C. Hale
Assistant Chief: Martha J. Frisone

Project ID #: F-11241-16
Facility: FMC Matthews
FID #: 080137
County: Mecklenburg
Applicant: Bio-Medical Applications of North Carolina, Inc.
Project: Add 2 dialysis stations for a total of 18 stations upon completion of this project, Project I.D. #F-11012-15 (add 8 stations), Project I.D. #F-10369-15 (delete 8 stations) and Project I.D. #F-11207-16 (relocate 5 stations to FKC Southeast Mecklenburg County)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Matthews proposes to add two dialysis stations for a total of 18 certified dialysis stations upon completion of this project, Project I.D. #F-11012-15 (add 8 stations), Project I.D. #F-10369-15 (delete 8 stations) and Project I.D. #F-11207-16 (relocate 5 stations to FKC Southeast Mecklenburg County).

Need Determination

The 2016 State Medical Facilities Plan (2016 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2016 Semiannual Dialysis Report (SDR), the county need

methodology shows there is a surplus of 13 dialysis stations in Mecklenburg County. Therefore, based on the county need methodology, there is no need for additional stations in Mecklenburg County. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate reported for FMC Matthews in the July 2016 SDR is 4.71 patients per station per week. This utilization rate was calculated based on 99 in-center dialysis patients and 21 certified dialysis stations as of December 31, 2015 (99 patients /21 stations = 4.71 patients per station per week). Application of the facility need methodology indicates that two additional stations are needed for this facility, as illustrated in the following table.

OCTOBER 1 REVIEW-JULY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/15		117.86%
Certified Stations		21
Pending Stations*		8
Total Existing and Pending Stations		**29**
In-Center Patients as of 12/31/15 (SDR2)		99
In-Center Patients as of 6/30/15 (SDR1)		99
Step	**Description**	
(i)	Difference (SDR2 - SDR1)	0
	Multiply the difference by 2 for the projected net in-center change	0
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/15	0
(ii)	Divide the result of step (i) by 12	0
(iii)	Multiply the result of step (ii) by 12 (the number of months from 12/31/14 until 12/31/15)	0
(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	99
(v)	Divide the result of step (iv) by 3.2 patients per station	30.94
	and subtract the number of certified and pending stations to determine the number of stations needed	**1.94**

*Eight dialysis stations will be added upon completion of Project I.D. #F-11012-15.

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is two stations. Rounding to the nearest whole number is allowed in Step (v) of the facility need methodology, as stated in the July 2016 SDR. Step (C) of the facility need methodology states, *"The facility may apply to expand to meet the need established …, up to a maximum of ten stations."* The applicant proposes to add two new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2016 SMFP which is applicable to this review: *Policy GEN-3: Basic Principles*. *Policy GEN-3*, on page 39, states:

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

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section B.4(a), page 12, Section O, pages 59-61, and Exhibit O-1. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote safety and quality.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section B.4(b), page 13, Section L, pages 51-53, and Exhibit L-1. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote equitable access.

Maximize Healthcare Value – The applicant describes how it believes the proposed project would maximize healthcare value in Section B.4(c) and (d), pages 14-16, Section C, pages 17-23, and Section N, page 57. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would maximize healthcare value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need as identified by the applicant. 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 July 2016 SDR and with *Policy GEN-3: Basic Principles*. 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.

The applicant, FMC Matthews, proposes to add two dialysis stations for a total of 18 certified dialysis stations upon completion of this project, Project I.D. #F-11012-15 (add 8 stations), Project I.D. #F-10369-15 (delete 8 stations) and Project I.D. #F-11207-16 (relocate 5 stations to FKC Southeast Mecklenburg County).

Patient Origin

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

In Section C.8, page 21, the applicant provides the historical in-center patient origin for FMC Matthews as of June 30, 2016, which is summarized in the following table:

FMC Matthews
Historical Patient Origin
June 30, 2016

County	In-Center
Mecklenburg	79
Union	12
TOTAL	**91**

In Section C.1, page 17, the applicant provides the projected patient origin for FMC Matthews for operating year one (OY1), Calendar Year 2019, and OY2, Calendar Year 2020, following completion of the project, as follows:

FMC Matthews
Projected Patient Origin

County	Operating Year One (OY1)	Operating Year Two (OY2)	County Patients as Percent of Total OY1	County Patients as Percent of Total OY2*
Mecklenburg	74.2	77.88	86.1%	86.1%
Gaston	12.0	12.0	14.5%	13.9%
Total*	86.2	89.9	101.0%	100.0%

*Totals may not foot due to rounding.

The applicant provides the assumptions and methodology used to project in-center patient origin in Section C.1, pages 17-18. The applicant adequately identifies the patient origin.

Analysis of Need

In Section B.4, page 12, the applicant states the application is filed pursuant to the facility need methodology in the 2016 SMFP, and utilizes data from the July 2016 SDR to apply the facility need methodology, in Section B.2, page 10, to demonstrate how the facility qualifies for two additional stations. In Section C.1, pages 17-18, the applicant provides the following assumptions:

1. The current patient population at FMC Matthews and who reside in Mecklenburg County are a part of the Mecklenburg County ESRD patient population as a whole and as such will increase at the Five Year Average Annual Change Rate (AACR) for Mecklenburg County of 5.0% as published in the July 2016 SDR.

2. As of June 30, 2016, 12 patients residing in Union County were dialyzing at FMC Matthews. It is assumed they will continue dialyzing at FMC Matthews, however no growth is calculated for patients residing in Union County.

3. Fifteen patients are projected to transfer from FMC Matthews to Fresenius Medical Care (FMC) Regal Oaks (Project I.D. #F-10369-15) upon completion of that project on December 31, 2016. Therefore, 15 patients will be subtracted from FMC Matthews.

4. Two patients will transfer from FMC Matthews to Fresenius Kidney Care (FKC) Southeast Mecklenburg County (Project I.D. #F-11207-16) upon completion of that project on December 31, 2018. Therefore, two patients will be subtracted from FMC Matthews.

5. The proposed project is to be completed on December 31, 2018.

6. The applicant projects that OY1 will be Calendar Year (CY) 2019 and OY2 will be CY 2020.

Projected Utilization

The applicant provides its methodology for projecting utilization for in-center patients for OY1 and OY2, in Section C.1, page 18, as follows:

	In-Center
The applicant begins with the Mecklenburg County in-patient census at the facility on June 30, 2016.	79
The Mecklenburg County in-center patient census is projected forward to December 31, 2016, increased by one-half the Five Year AACR for Mecklenburg County of 5%.	{79 x (0.05/12 x 6)} + 79 = 80.98
The applicant subtracts 15 in-center patients who will transfer to FMC Regal Oaks.	80.98 – 15 = 65.98
The census of Mecklenburg County in-center patients is increased by the Five Year AACR for Mecklenburg County of 5% to project the census forward one year to December 31, 2017.	(65.98 x 0.05) + 65.98 = 69.27
The census of Mecklenburg County in-center patients is increased by the Five Year AACR for Mecklenburg County of 5% to project the census forward one year to December 31, 2018.	(69.27 x 0.05) + 69.27 = 72.7
Two Mecklenburg County patients transfer to FKC Southeast Mecklenburg County and are, therefore, subtracted.	72.7 – 2 = 70.7
The applicant adds 12 patients from Union County for the beginning census for OY1.	70.7 + 12 = 82.7
The census of Mecklenburg County in-center patients only is projected forward one year and increased by the Five Year AACR for Mecklenburg County of 5% to December 31, 2019.	(70.7 x 0.05) + 70.7 = 74.3
The applicant adds 12 patients from Union County for the ending census of OY1.	74.3 + 12 = 86.3
The census of Mecklenburg County in-center patients only is projected forward one year and increased by the Five Year AACR for Mecklenburg County of 5% to December 31, 2020.	(74.3 x 0.05) + 74.3 = 78.0
The applicant adds 12 patients from Union County for the ending census of OY2.	78.0 + 12 = 90.0

The applicant projects to serve 86 in-center patients or 4.78 patients per station per week (86 patients/ 18 dialysis stations = 4.78) by the end of OY1. The applicant states, in Section C.1, page 19, that the number of patients to be served at the end of OY1 is rounded down. Therefore, the applicant's projected utilization exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

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

Access

In Section C.3, pages 19-20, the applicant states that BMA has a long history of serving the underserved population in the state and that each facility serves *"low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons."* The applicant further states that BMA will continue to provide access to all persons, including low income and medically underinsured persons. In Section L.7, page 55, the applicant states that 81.9% of FMC Matthews's patients were Medicare or Medicaid recipients in CY2015. In Section L.1, page 52, the applicant projects that 81.7% of its patients will be Medicare or Medicaid recipients. The applicant adequately demonstrates the extent to which all residents of the service area, including underserved groups, are likely to have access to its services.

Conclusion

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

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

NA

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

CA

In Section E.1, page 25, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

- Maintain the Status Quo –The applicant states that the facility's projected utilization is over 80% of capacity and that maintaining the status quo would result in higher utilization rates and may restrict patient admissions. Therefore, this is not the most effective alternative.
- Apply for Fewer Stations – The applicant states that based on its application of the facility need methodology, it is eligible for up to two additional dialysis stations and that even with these two stations it is projected to exceed 100% utilization. Therefore, fewer stations would not address the need. Therefore, this is not the most effective alternative.

- Provide Home Training – The applicant states that there is not enough room at the facility to provide this training. Therefore, this is not the most effective alternative.
- Relocate stations to FMC Matthews – The applicant states it considered relocating dialysis stations from other BMA facilities in Mecklenburg County to FMC Matthews, however all of the other facilities are operating at over 80% of capacity. Therefore, this is not the most effective alternative.

In Section C.2, page 19, the applicant states that the projected population at FMC Matthews has a need for the additional stations and that *"failure to add the two stations will lead to higher utilization rates at the facility."* The applicant states, in Section E.1, page 25, that its proposal to add two stations to FMC Matthews is most appropriate. Therefore, the proposed alternative represented in the application is the most effective alternative to meet the identified need.

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

In summary, the applicant adequately demonstrates that the 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 two additional dialysis stations for a total of no more than 18 certified stations upon completion of the project, Project I.D. #F-11012-15 (add 8 stations), Project I.D. #F-10369-15 (delete 8 stations) and Project I.D. #F-11207-16 (relocate 5 stations to FKC Southeast Mecklenburg County), which shall include any isolation or home hemodialysis 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 Healthcare Planning and Certificate of Need Section in writing prior to issuance of the certificate of need.**

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

C

The applicant, FMC Matthews, proposes to add two dialysis stations for a total of 18 certified dialysis stations upon completion of this project, Project I.D. #F-11012-15 (add 8 stations),

Project I.D. #F-10369-15 (delete 8 stations) and Project I.D. #F-11207-16 (relocate 5 stations to FKC Southeast Mecklenburg County).

Capital and Working Capital Costs

In Section F.2, page 27, the applicant states that it will not incur any capital costs to develop the project. In Sections F.10-F.12, page 30, the applicant states there will be no start-up expenses or initial operating expenses incurred for this project.

Financial Feasibility

The applicant provides pro forma financial statements for the first two years of the project. In the pro forma financial statement (Form B), the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

	OY1 (CY2019)	OY2 (CY2020)
Total Net Revenue	$8,992,677	$9,421,073
Total Operating Expenses	$5,716,382	$4,956,813
Net Income	**$3,276,295**	**$4,464,260**

In Section H.1, page 38, the applicant provides projected staffing and salaries. The discussion regarding staffing found in Criterion (7) is incorporated herein by reference. The applicant adequately demonstrates the availability of sufficient funds for the operating needs of the project and that the financial feasibility of the proposal is based upon reasonable and adequately supported assumptions regarding projected utilization, revenues (charges) and operating costs. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

In summary, the applicant adequately demonstrates the availability of sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. 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, FMC Matthews, proposes to add two dialysis stations for a total of 18 certified dialysis stations upon completion of this project, Project I.D. #F-11012-15 (add 8 stations), Project I.D. #F-10369-15 (delete 8 stations) and Project I.D. #F-11207-16 (relocate 5 stations to FKC Southeast Mecklenburg County).

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

According to the July 2016 SDR, there are 21 dialysis facilities in Mecklenburg County. Of these, 16 are operational, four are under development, and one has certified stations but is not yet operational. The applicant or its parent company owns and operates 10 of the 21 dialysis facilities in Mecklenburg County. DVA Healthcare Renal Care, Inc. (DaVita) owns and operates eight facilities, DSI Renal, Inc. (DSI) operates two facilities, and Carolinas Medical Center (DMC) operates one facility, as shown in the table below.

Mecklenburg County Dialysis Facilities
Certified Stations and Utilization as of December 31, 2015

Facility	Owner	Location	Number of Existing/ Approved Stations	Utilization as of December 31, 2015
BMA Beatties Ford	BMA	Charlotte	32	99.22%
BMA FMC Matthews	BMA	Charlotte	28	102.68%
BMA of East Charlotte	BMA	Charlotte	25	85.00%
BMA of North Charlotte	BMA	Charlotte	28	103.57%
BMA West Charlotte	BMA	Charlotte	29	87.07%
Brookshire Dialysis	DaVita	Charlotte	10	0.00%
Carolinas Medical Center	CMHA	Charlotte	9	27.78%
Charlotte Dialysis	DaVita	Charlotte	36	88.89%
Charlotte East Dialysis	DaVita	Charlotte	26	108.65%
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	55.21%
DSI Glenwater Dialysis	DSI	Charlotte	41	81.71%
FMC Charlotte	BMA	Charlotte	43	82.56%
FMC Matthews	BMA	Matthews	21	117.86%
FMC of Southwest Charlotte*	BMA	Charlotte	10	0.00%
FMC Regal Oaks*	BMA	Charlotte	12	0.00%
FMC Aldersgate*	BMA	Charlotte	10	0.00%
Huntersville Dialysis**	DaVita	Huntersville	10	0.00%
Mint Hill Dialysis	DaVita	Mint Hill	12	93.75%
North Charlotte Dialysis Center	DaVita	Charlotte	41	92.68%
South Charlotte Dialysis	DaVita	Charlotte	22	80.68%
University City Dialysis*	DaVita	Charlotte	10	0.00%

*Facility under development.
**Facility has certified stations but is not yet operational.

As shown in the table above, all seven of BMA's operational dialysis facilities are operating above 80% utilization (3.2 patients per station per week). Three of BMA's dialysis facilities are under development. Only two of the 16 operational dialysis facilities in the county are operating below 80% utilization, a DSI facility and a CMC facility.

According to Table B in the July SDR, there is a surplus of 13 dialysis stations in Mecklenburg County. However, the applicant is applying for additional stations based on the facility need methodology. As of December 31, 2015, FMC Matthews was serving 99 patients on 21 dialysis stations per week, which is 4.71 patients per station per week or 117.86% of capacity. The applicant does not propose to establish a new facility. In Section C.1, pages 18-19, of the application, the applicant adequately demonstrates that FMC Matthews will serve a total of 86 in-center patients on 18 dialysis stations at the end of OY1 (CY2019), for a utilization rate of 4.78 patients per station per week, or 119.50% of capacity (86/ 18 = 4.78; 4.78/4 = 119.5%). Therefore, the facility is expected to serve more than 3.2

patients per station per week at the end of the first operating year as required by 10A NCAC 14C .2203(b).

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved dialysis stations or facilities. Therefore, the application is conforming to this criterion.

(7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

In Section H.1, page 38, the applicant provides the current staffing for the facility, which includes 23.45 full-time equivalent (FTE) employees, and the proposed staffing for the facility following completion of the project, which will not change. In Section H.3, page 39, the applicant describes its experience and process for recruiting and retaining staff, and states that its recruiting and advertising efforts have enabled the facility to maintain staffing levels. Exhibit I-5 contains a copy of a letter from Edward Carl Fisher, Jr., M.D., stating that he has agreed to continue serving as the Medical Director for the facility. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed 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.1, page 41, the applicant includes a list of providers of the necessary ancillary and support services. Exhibits I-1 and I-2 contain copies of agreements regarding home training and laboratory services, respectively. The applicant states, in Section I.4, page 44, that it has an agreement with Carolinas Medical Center for hospital services and acute dialysis care. In addition, on page 44, it states that it has an agreement with CMC for transplantation services.

In Section I.3, pages 43-44, the applicant states that BMA and the nephrologists at Metrolina Nephrology Associates have a long history of serving the needs of dialysis patients in the area and that BMA has forged relationships with physicians, local hospitals, and other health professionals within the community. In addition, the applicant states, in Section I.4, page 44, that it has an informal agreement with Sanger Heart and Vascular for dialysis access surgeries and care. Moreover, Exhibit I-5 contains a letter from the medical director of the facility that expresses his support for the proposed project.

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

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

NA

(10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

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

NA

(11) Repealed effective July 1, 1987.

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

NA

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

(a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L.7, page 55, the applicant reports that 81.91% of the in-center patients who received treatments at FMC Matthews had some or all of their services paid for by Medicare or Medicaid in CY2015. The table below shows the historical (CY2015) payment source for the facility for in-center patients:

Payment Source	In-Center
Private Pay	1.25%
Commercial Insurance	14.47%
Medicare	60.51%
Medicaid	2.37%
Misc., including VA	2.37%
Medicare/Commercial Insurance	19.03%
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 & Ethnic Minority***	**% Persons in Poverty****	**% < Age 65 with a Disability**	**% < Age 65 without Health Insurance****
Mecklenburg	10%	52%	51%	15%	6%	19%
Statewide	15%	51%	36%	17%	10%	15%

Source: http://www.census.gov/quickfacts/table, 2014 Estimate as of December 22, 2015.
*Excludes *"White alone"* who are *"not Hispanic or Latino"*
***"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable…The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."*

The *Southeastern Kidney Council Network 6 Inc. Annual Report* provides prevalence data on North Carolina dialysis patients by age, race, and gender on page 59, summarized as follows:

Number and Percent of Dialysis Patients by Age, Race, and Gender 2014		
	# of ESRD Patients	**% of Dialysis Population**
Age		
0-19	52	0.3%
20-34	770	4.8%
35-44	1,547	9.7%
45-54	2,853	17.8%
55-64	4,175	26.1%
65+	6,601	41.3%
Gender		
Female	7,064	44.2%
Male	8,934	55.8%
Race		
African-American	9,855	61.6%
White	5,778	36.1%
Other, inc. not specified	365	2.3%

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

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

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

(b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

In Section L.3, page 53, the applicant states:

> *"BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations. ... The applicant will treat all patients the same regardless of race or handicap status."*

In Section L.6, page 54, the applicant states there have been no civil rights complaints filed against any BMA North Carolina facility in the past five years. Therefore, the application is conforming to this criterion.

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

C

In Section L.1(b), page 52, the applicant projects that 81.7% of the in-center patients who will receive treatments at FMC Matthews in OY2, calendar year (CY) 2020 will have some or all of their services paid for by Medicare or Medicaid. The table below shows the projected OY2 payor mix for the facility for in-center patients:

FMC Matthews
Projected Payor Mix, OY2 (CY2020)

Payment Source	Percent of In-Center Patients
Private Pay	1.64%
Commercial Insurance	14.70%
Medicare	61.61%
Medicaid	1.27%
VA	1.97%
Medicare/Commercial Insurance	18.82%
Total	**100.00%**

*Total may not foot due to rounding.

In Section L.1, page 52, the applicant provides the assumptions used to project payor mix. The applicant's projected payor mix is similar to the facility's historical (CY2015) payment mix as reported by the applicant in Section L.7, page 55. The applicant demonstrates that medically underserved groups will have adequate access to the services offered at FMC Matthews. Therefore, the application is conforming to this criterion.

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

C

In Section L.4, page 54, the applicant describes the range of means by which a person will have access to the dialysis services at FMC Matthews. Any nephrologist may apply for privileges to admit patients and they make take referrals from other nephrologists, other physicians, or hospital emergency rooms. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to dialysis services. 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.1, page 56, the applicant states that BMA has communicated with local nursing programs, inviting them to utilize FMC Matthews in their clinical rotations for nursing students. Exhibit M-1 contains a copy of correspondence to Central Piedmont Community College offering FMC Matthews as a clinical training site for the college's nursing students. The information provided is reasonable and adequately supports a determination that the application is conforming 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

The applicant, FMC Matthews, proposes to add two dialysis stations for a total of 18 certified dialysis stations upon completion of this project, Project I.D. #F-11012-15 (add 8 stations), Project I.D. #F-10369-15 (delete 8 stations) and Project I.D. #F-11207-16 (relocate 5 stations to FKC Southeast Mecklenburg County).

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

According to the July 2016 SDR, there are 21 dialysis facilities in Mecklenburg County. Of these, 16 are operational, four are under development, and one has certified stations but is not yet operational.

Mecklenburg County Dialysis Facilities
Certified Stations and Utilization as of December 31, 2015

Facility	Owner	Location	Number of Existing/ Approved Stations	Utilization as of December 31, 2015
BMA Beatties Ford	BMA	Charlotte	32	99.22%
BMA FMC Matthews	BMA	Charlotte	28	102.68%
BMA of East Charlotte	BMA	Charlotte	25	85.00%
BMA of North Charlotte	BMA	Charlotte	28	103.57%
BMA West Charlotte	BMA	Charlotte	29	87.07%
Brookshire Dialysis	DaVita	Charlotte	10	0.00%
Carolinas Medical Center	CMHA	Charlotte	9	27.78%
Charlotte Dialysis	DaVita	Charlotte	36	88.89%
Charlotte East Dialysis	DaVita	Charlotte	26	108.65%
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	55.21%
DSI Glenwater Dialysis	DSI	Charlotte	41	81.71%
FMC Charlotte	BMA	Charlotte	43	82.56%
FMC Matthews	BMA	Matthews	21	117.86%
FMC of Southwest Charlotte*	BMA	Charlotte	10	0.00%
FMC Regal Oaks*	BMA	Charlotte	12	0.00%
FMC Aldersgate*	BMA	Charlotte	10	0.00%
Huntersville Dialysis**	DaVita	Huntersville	10	0.00%
Mint Hill Dialysis	DaVita	Mint Hill	12	93.75%
North Charlotte Dialysis Center	DaVita	Charlotte	41	92.68%
South Charlotte Dialysis	DaVita	Charlotte	22	80.68%
University City Dialysis*	DaVita	Charlotte	10	0.00%

*Facility under development.
**Facility has certified stations but is not yet operational.

As shown in the table above, all seven of BMA's operational dialysis facilities are operating above 80% utilization (3.2 patients per station per week). Three of BMA's dialysis facilities are under development. Only two of the 16 operational dialysis facilities in the county are operating below 80% utilization, a DSI facility and a CMC facility.

In Section N.1, page 57, the applicant discusses how any enhanced competition will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states,

> *"BMA facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid. The majority of our patients rely upon Medicare and Medicaid to cover the expense of their treatments. In this application, BMA projects that greater than 74% of the In-center patients will be relying upon government payors (Medicare /Medicaid). 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. ... This proposal will certainly not adversely affect quality, but rather, enhance the quality of the ESRD patients' lives by offering another convenient venue for dialysis care and treatment."

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

The information in the application 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 project and that it is a cost-effective alternative. The discussions regarding the analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.

- The applicant adequately demonstrates it will provide quality services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.

- The applicant demonstrates that it will provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (1), (3) and (13) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

(19) Repealed effective July 1, 1987.

(20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Exhibit A-4, the applicant identifies the kidney disease treatment centers located in North Carolina that it or an affiliated company owns and operates. In Section O.3, page 62, the applicant identifies three of its facilities, BMA Lumberton, BMA East Charlotte, and RAI West College – Warsaw that were cited in the past 18 months for deficiencies in compliance with 42 CFR Part 494, the Centers for Medicare and Medicaid (CMS) Conditions for Coverage of ESRD facilities. The applicant states, on page 64, that all three facilities are back in full compliance with CMS Guidelines as of the date of submission of this application. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. The 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 promulgated in 10A NCAC 14C .2200. The specific criteria are discussed below:

10 NCAC 14C .2203 PERFORMANCE STANDARDS

.2203(a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*

-NA- 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 C.1, page 17, the applicant projects to serve 86 in-center patients by the end of OY1, which is 4.78 patients per station per week (86/ 18 = 4.78). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

-C- In Section C.1, pages 17-19, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.