

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: November 29, 2016

Findings Date: November 29, 2016

Project Analyst: Bernetta Thorne-Williams

Team Leader: Fatimah Wilson

Project ID #: F-11242-16

Facility: Metrolina Kidney Center

FID #: 955949

County: Union

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

Project: Add five dialysis stations for a total of 16 dialysis stations and develop a peritoneal and home hemodialysis training program upon completion of this project and Project I.D. F-11208-16 (relocate 10 stations to develop a new facility)

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 Metrolina Kidney Center (“the applicant”) proposes to add five dialysis stations for a total of 16 certified dialysis stations and develop a peritoneal and home hemodialysis training program upon completion of this project and Project I.D. # F-11208-16 (relocate ten dialysis stations from Metrolina Kidney Center to develop a new ten station facility).

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 deficit of six dialysis stations in Union County. The applicant has opted not to apply for additional stations based on the county need methodology. However, the applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. The applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate reported for Metrolina Kidney Center in the July 2016 SDR is 3.5714 patients per station per week, or 89.29% (3.5714/4 patients per station = 0.89285). This utilization rate was calculated based on 75 in-center dialysis patients and 21 certified dialysis stations (75 patients / 21 stations = 3.5714 patients per station per week).

Application of the facility need methodology indicates additional stations are needed for this facility, as illustrated in the following table:

OCTOBER 1 REVIEW-JULY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/15		89.3%
Certified Stations		21
Pending Stations		0
Total Existing and Pending Stations		21
In-Center Patients as of 12/31/15 (July 2016 SDR) (SDR2)		75
In-Center Patients as of 6/30/15 (Jan 2016 SDR) (SDR1)		66
Step	Description	Result
	Difference (SDR2 - SDR1)	9
(i)	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 6/30/15	0.2727
(ii)	Divide the result of Step (i) by 12	0.0227
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/14 until 12/31/15)	0.2727
(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	95.4545
(v)	Divide the result of Step (iv) by 3.2 patients per station	29.8295
	and subtract the number of certified and pending stations to determine the number of stations needed	8.8295

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is nine 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 five new stations, therefore the application 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* on page 39 of the 2016 SMFP is applicable to this review because the facility need methodology is applicable to this review. Policy GEN-3 states:

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

Promote Safety and Quality

The applicant describes how it believes the proposed project would promote safety and quality in Section B.4, page 12 and Section O, pages 62-64. 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, page 13, Section C, pages 21-22, Section L, pages 54-57 and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project would maximize healthcare value in Section B, pages 14-17, Section N, pages 60-61, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

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

Conclusion

In summary, the applicant adequately demonstrates that the proposal is consistent with the facility need methodology in the July 2016 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 five dialysis station for a total of 16 certified dialysis stations and develop a peritoneal and home hemodialysis training program at the Metrolina Kidney Center upon completion of this project and Project I.D. # F-11208-16 (relocate ten dialysis stations from Metrolina Kidney Center to develop a new ten station facility).

Patient Origin

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

In Section C, page 25, the applicant provides a table showing the historical patient origin for in-center (IC) patients served by Metrolina Kidney Center, as shown below:

Dialysis Patients as of 6/30/2016

COUNTY	IC PATIENTS
Union	74
Anson	1
South Carolina	1
Total	76

In Section C, page 18, the applicant identifies the patient population it proposes to serve during the first two years of operation following project completion, as illustrated in the table below:

COUNTY	OPERATING YEAR 1 CY 2019			OPERATING YEAR 2 CY 2020			COUNTY PATIENTS AS % OF TOTAL	
	IC	HH	PD	IC	HH	PD	OY 1	OY 2
Union	54.2	1.00	1.00	57.1	2.09	2.09	96.4%	96.6%
Anson	1.0	0.0	0.0	1.0	0.0	0.0	1.7%	1.6%
South Carolina	1.0	0.0	1.0	1.0	0.0	0.0	1.7%	1.6%
Total	56.2	1.00	1.00	59.1	2.10	2.10	100.0%	100.0%

The applicant provides the assumptions and methodology for the projections above on pages 18-21.

The applicant adequately identifies the population it proposes to serve.

Analysis of Need

The applicant proposes to add five dialysis stations to the existing Metrolina Kidney Center facility for a total of 16 certified dialysis stations and develop a peritoneal and home hemodialysis training program upon completion of this project and Project I.D. # F-11208-16.

1. In Section B.2, page 10, the applicant states the application is filed pursuant to the facility need methodology in the 2016 SMFP utilizing data from the July 2016 SDR.
2. In Section C.1, pages 18-19, the applicant provides the assumptions used to demonstrate the need for the project, summarized as follows:

Metrolina Kidney Center census has been increasing at a rate greater than the Five-Year Average Annual Change Rate for Union County of 7.4%. The applicant states that the Facility Need Methodology calculates a growth rate in excess of 27.0% for this facility. Thus, the applicant will use a slightly higher rate of 9% which is less than one third of the demonstrated growth, but more appropriate than the published growth rate.

3. The applicant does not project growth of any patients residing outside of Union County; these patients will be added into the projections of future patient populations at appropriate points in time.
4. Operating Year 1 = January 1 – December 31, 2019 (CY2019)
Operating Year 2 = January 1 – December 31, 2020 (CY2020)

Projected Utilization

In Section C, page 20, the applicant provided the methodology used to project in-center utilization, as illustrated in the following table,

Begin with the Union County patients dialyzing at Metrolina Kidney Center as of June 30, 2016.	74
Project the Union County patient population forward for six months to December 31, 2016.	$[74 \times (.09 / 125 \times 6)] + 74 = 77.3$
Project this patient population forward one year to December 31, 2017.	$(77.3 \times .09) + 77.3 = 84.257$
Subtract 37 patients transferring to FKC Indian Trail and FKC Southeast Mecklenburg County	$84.3 - 37 = 47.3$
Project this patient population forward one year to December 31, 2018.	$(47.3 \times .09) + 47.3 = 51.55$
Add two patients from Anson County and South Carolina. This is the start census.	$51.55 + 2 = 53.5$
Project this patient population of Union County forward one year to December 31, 2019.	$(51.55 \times .09) + 51.55 = 56.2$
Subtract two patients projected to change modality to home based dialysis.	$56.2 - 2 = 54.2$
OY1: Add two patients from outside the county. This is the projected ending census for Operating Year 1.	$54.2 + 2 = 56.2$
Project the Union County patient population forward one year to December 31, 2020.	$(54.2 \times .09) = 54.2 = 59.1$
Subtract two patients projected to change modality to home based dialysis and add two patients from outside the county.	$59.1 - 2 = 57.1$
OY2: Add the patients currently dialyzing from Mecklenburg County. This is the projected ending census for Operating Year 2.	$57.1 + 2 = 59.1$

The applicant demonstrates that Metrolina Kidney Center will serve a total of 56 in-center patients at the end of Operating Year One for a utilization rate of 87.5% or 3.5 patients per station per week (56 patients / 16 stations = 3.5 / 4 = 0.875 or 87.5%). The projected utilization

of 3.5 patients per station per week at the end of OY1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

Home Hemodialysis and Peritoneal Dialysis

On page 20 of the application, the applicant projects that in each of the first two years that two patients would transition from in-center dialysis care to home dialysis care, as shown below:

*“Operating Year 1: 1 PD patient 1 HH patient
Operating Year 2: 2 PD patients 2 HH patients”*

The applicant further states on page 20, that six home dialysis patients are projected to transfer their care from other BMA facilities to Metrolina Kidney Center, thus, the applicant projects the following home patient population in OY1 and OY2:

*“Operating Year 1: 5 PD patient 3 HH patient
Operating Year 2: 6 PD patients 2 HH patients”*

On page 19 the applicant states that FMC Charlotte currently provides services to two home hemodialysis patients and four peritoneal patients that reside in Union County. The applicant projects that these patients will transfer their care to Metrolina Kidney Center upon project completion.

Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth at Metrolina Dialysis Center upon project completion.

Access

In Section L, pages 54-55, the applicant states that each of BMA’s 105 facilities in 42 North Carolina counties has a patient population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, and other traditionally underserved persons. The applicant provides its historical payor mix for CY2015 on page 58, as illustrated below.

Payment Source	Percent of Total Patients
Private Pay	9.82%
Commercial Insurance	7.38%
Medicare	64.40%
Medicaid	7.36%
Miscellaneous (Incl. VA)	5.02%
Other: Medicare/Commercial Insurance	6.02%
Total	100.00%

On page 55, the applicant projects that 73.9% 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, adequately demonstrates the need that population has for the services proposed and the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services. Therefore, the application is conforming to this criterion.

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

NA

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

CA

In Section E-1, page 28, the applicant discusses the alternatives considered prior to submitting this application, which include:

1. Maintain the Status Quo - the applicant states that this option would result in higher utilization rates and would not be in the best interest of those patients currently dialyzing at the facility.
2. Apply for Fewer Stations - Application of the facility need methodology indicated a need for an additional nine stations. However, the applicant opted to apply for five additional stations which the applicant states will meet the growing need for additional stations at Metrolina Kidney Center.
3. Not Developing a Home Dialysis Program – The applicant concluded that to continue to have its patients travel to Charlotte for home dialysis training was not in the best interest of those patients currently dialyzing at Metrolina Kidney Center.

After considering the above alternatives, the applicant states that development of the project, as proposed in the application, would reduce the transportation demands faced by existing patients in

need of home dialysis training and increase the patients' quality of life and compliance with treatment schedules. Therefore, BMA believes that adding five dialysis stations and developing a home training program at Metrolina Kidney Center will address the growing dialysis population at its facilities in Union County and is, therefore, 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 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 Metrolina Kidney Center shall materially comply with all representations made in the certificate of need application.**
 - 2. Bio-Medical Applications of North Carolina, Inc. d/b/a Metrolina Kidney Center shall develop and operate no more than five additional dialysis stations at Metrolina Kidney Center for a total of no more than 16 certified dialysis stations which shall include any isolation or home hemodialysis training stations upon completion of this project and Project I.D. # F-11208-16.**
 - 3. Bio-Medical Applications of North Carolina, Inc. d/b/a Metrolina Kidney Center shall install plumbing and electrical wiring through the walls for no more than five additional dialysis stations, which shall include any isolation or home hemodialysis training stations.**
 - 4. Bio-Medical Applications of North Carolina, Inc. d/b/a Metrolina Kidney Center 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

BMA proposes to add five dialysis stations for a total of 16 certified dialysis stations and develop a home training program at the Metrolina Kidney Center facility upon completion of this project and Project I.D. # F-11208-16.

Capital and Working Capital Costs

In Section F, page 30, the applicant projects the capital cost for the proposed project, as summarized in the table below:

Construction Contract	\$1,452,215
Equipment/furniture not included above	\$127,470
Total	\$1,579,685

In Section F, pages 33-34, the applicant states that there are no working capital needs for the proposed project since Metrolina Kidney Center is an existing facility.

Availability of Funds

In Section F, page 31, the applicant states that accumulated reserves will be used to finance the proposed project. In Exhibit F-1 the applicant provides a letter dated September 15, 2016, from The Senior Vice President and Treasurer, Fresenius Medical Care Holdings, Inc., (FMC) which is the parent of National Medical Care, Inc. and Bio-Medical Applications of North Carolina, Inc., confirming FMC's commitment to funding the project's capital with cash reserves.

Exhibit F-2 contains a copy of Fresenius Medical Care Holdings, Inc. and Subsidiaries (FMC) Consolidated Financial Statements for December 31, 2015 and December 31, 2014. As of December 31, 2015, FMC had \$249,300,000 in cash and cash equivalents, \$19,332,539 in total assets and \$10,144,288 in net assets (total assets less total liabilities). (See Exhibit F-2, page 3)

The applicant adequately demonstrated the availability of sufficient funds for the capital and working capital needs of the project.

Financial Feasibility

In Section R, Form C, the applicant provides its allowable charge per treatment for each payment source and provides its operating expense and revenue assumptions in Forms A-C.

The applicant projects revenues in Section R, Form B, and operating expenses in Section R, Form A, summarized in the table below:

METROLINA KIDNEY CENTER	OPERATING YEAR 1 CY 2019	OPERATING YEAR 2 CY 2020
Total Net Patient Revenue	\$2,555,633	\$3,022,483
Total Operating Expenses	\$2,484,086	\$2,775,084
Net Income	\$71,547	\$247,399

*Note: Union County Dialysis has submitted an application, Project F-11259-16 to add two dialysis stations for a total of 30 inpatient dialysis stations upon project completion.

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. Supported assumptions regarding projected utilization, revenues (charges) and operating costs. See Section R, pro formas, for the applicant’s assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

In Section H.1, page 40, the applicant provides projected staffing and salaries. Form A in Section R, shows budgeted operating costs adequate to cover the projected staffing. The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

Conclusion

In summary, the applicant adequately demonstrates that sufficient funds will be available for the capital and operating needs of the project. Furthermore, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

BMA proposes to add five dialysis stations for a total of 16 certified dialysis stations and develop a home training program at the Metrolina Kidney Center following completion of this project and Project I.D. # F-11208-16 (relocate ten dialysis stations from Metrolina Kidney Center to develop a new ten station facility).

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

The July 2016 SDR indicates there are three dialysis facilities in Union County, as follows:

**Union County Dialysis Facilities
 December 31, 2015**

Dialysis Facilities	Owner	# of Patients	Location	# of Certified Stations	# of Approved Stations	Percent Utilization
Marshville Dialysis	DVA	31	Marshville	12	0	64.58%
Metrolina Kidney Center	BMA	75	Monroe	21	0	89.29%
Union County Dialysis	DVA	92	Monroe	28	0	82.14%

*Note: Union County Dialysis has submitted an application, Project F-11259-16 to add two dialysis stations for a total of 30 inpatient dialysis stations upon project completion.

As shown in the table above two of the three facilities in Union County are operated by DVA. Based on the most recent SDR, two of the three facilities operated in Union County operated at 80.0% utilization or above.

In Section C, pages 18-20, the applicant demonstrates that Metrolina Kidney Center will serve a total of 56 in-center patients at the end of Operating Year One for a utilization rate of 87.5% or 3.5 patients per station (56 patients / 16 stations = 3.5 / 4 = .875 or 87.5%). The projected utilization of 3.5 patients per station per week for Operating Year One exceeds the 3.2 in-center patients per station threshold as required by 10A NCAC 14C .2203(b).

The applicant states that the projected utilization rates are based on patients currently dialyzing at Metrolina Kidney Center. The applicant provides in methodology for its proposed home training program on page 30, of the application.

The applicant adequately demonstrates the need to add five additional stations at Metrolina Kidney Center based on the number of in-center patients it proposes to serve. Additionally, the applicant also demonstrates the need to add a home training program to Metrolina Kidney Center. The discussion on analysis of need found in Criterion (3) is incorporated herein by reference. The discussion on competition found in Criterion (18a) is 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 Union County. Consequently, the application is conforming to this criterion.

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

In Section H, page 40, the applicant provides the following table to illustrate current and projected staffing in full time equivalents (FTEs) for Metrolina Kidney Center. The applicant states the Medical Director is not employed by the facility, and thus is not reflected on the staffing chart.

POSITION	CURRENT # FTEs	# FTEs POSITIONS ADDED/ DELETED	PROJECTED # FTEs
Registered Nurse	3.50	-0.75	2.75
Technician (PCT))	8.00	-2.00	6.00
Clinical Manager	1.00		1.00
Administrator	0.20		0.20
Dietician	0.65	-0.15	0.50
Social Worker	0.65	-0.15	0.50
Home Training RN		0.50	0.50
Chief Tech	0.15		0.15
Equipment Tech	0.75		0.75
In-Service	0.20		0.20
Clerical	1.00		1.00
Total	16.10	-3.55	13.55

In Section H, page 43, the applicant provides the projected direct care staff for Metrolina Kidney Center in Operating Year 2, as shown below in the table:

DIRECT CARE POSITIONS	# FTEs	HOURS PER YEAR PER FTE	TOTAL ANNUAL FTE HOURS	TOTAL ANNUAL HOURS OF OPERATION	# FTE HOURS PER HOUR OF OPERATION
Registered Nurse	2.75	2,080	5,720	3,432	1.67
Technician (PCT)	6.00	2,080	12,480	3,432	3.64
Home Training RN	0.50	2,080	1,040	3,432	0.30
Total	9.25	2,080	19,240	3,432	5.61

In Section I, page 45, the applicant identifies Dr. Andrew S. O'Connor as the Medical Director of the facility. In Exhibit I-6, the applicant provides a copy of a letter signed by Dr. O'Connor of Metrolina Nephrology Associates, PA supporting the project and confirming his commitment to serve as Medical Director. In Section H, pages 41, the applicant describes the methods used to recruit and fill vacant or new positions.

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

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

C

In Section I, page 44, the applicant includes a list of providers of the necessary ancillary and support services. Exhibit I-6 contains a letter from the medical director of the facility expressing his support for the proposed project. The applicant discusses coordination with the existing health care system on pages 44-47. Exhibits I-3 through I-5, respectively, contain copies of agreements for Spectra laboratories services, Mercy Hospital, Inc., and Duke University Medical Center for transplant services. The information in Section I and Exhibits I-1, I-2 and I-3 is reasonable and adequately supports a finding of conformity with 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.

C

BMA proposes to add five dialysis stations for a total of 16 certified dialysis stations and develop a home training program at the Metrolina Kidney Center following completion of this project and Project I.D. # F-11208-16 (relocate ten dialysis stations from Metrolina Kidney Center to develop a new ten station facility).

In Section K.2, page 51, the applicant states the facility currently consist of 3,080 square feet of treatment area, which includes space for an isolation room. Upon project completion the facility will consist of 3,632 square feet including 552 square feet of space renovated/converted to service as the training area for home hemodialysis and peritoneal training,. The applicant provides line drawings Exhibit K.1. In Section F.1, page 30, the applicant list its project cost including \$1,452,215 for construction contract costs and \$127,470 for equipment costs for a total of \$1,579,685.

Costs and charges are described by the applicant in Section F, pages 30-31, and in Section R pro forma financial statements. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference.

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, that energy saving features have been incorporated into the construction plans and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion

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

C

In Section L, page 58, the applicant reports that 77.78% of the patients who received treatments at Metrolina Kidney Center had some or all of their services paid for by Medicare or Medicaid in CY 2015, as illustrated in the table below.

Payment Source	Percent of Total Patients
Private Pay	9.82%
Commercial Insurance	7.38%
Medicare	64.40%
Medicaid	7.36%
Miscellaneous (Incl. VA)	5.02%
Other: Medicare/Commercial Insurance	6.02%
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**
Union	11%	51%	27%	11%	6%	16%
Anson	16%	48%	55%	25%	15%	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://www.esrdnetwork6.org/utills/pdf/annual-report/2014%20Network%206%20Annual%20Report.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 adequately 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 57, the applicant states:

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

In Section L.6, page 57, the applicant states that there have been no Civil Rights complaints filed against any BMA North Carolina facilities in the past five years.

The application is conforming to this criterion.

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

C

In Section L.1, page 54, the applicant states:

“It is BMA policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.”

In Section L, page 55, the applicant projects that 73.9% of all patients who will receive dialysis treatments at Metrolina Kidney Center will have all or part of their services paid for by Medicare and or Medicaid, which is a slight decrease from its historical payor source, as illustrated below:

**Metrolina Dialysis Center
Projected Payor Mix OY2**

Payor Type	Percent of Total Patients	Percent of IC	Percent of HH	Percent of PD
Medicare	62.3%	64.32%	64.32%	52.18%
Medicaid	5.8%	7.33%	7.33%	3.21%
Commercial Insurance	14.5%	7.80%	7.80%	38.15%
Medicare/Commercial	5.8%	5.97%	5.97%	2.40%
VA	4.30%	5.11%	5.11%	0.0
Self/Indigent/Charity	7.20%	9.47%	9.47%	4.05%
Total	100.00%	100.00%	100.00%	100.00%

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 L.4, page 57, the applicant states:

“Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. [Metrolina Kidney Center] has an open policy, which means that any Nephrologist may apply to admit patient to the facility. The attending physicians receive referrals from other physicians or Nephrologists or hospital emergency rooms. ... Transient patients are accepted upon proper coordination of care with the patient’s regular nephrologist and a physician with staff privileges at the facility.”

The applicant adequately demonstrates that 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 M, page 59 the applicant states that Metrolina Kidney Center has an agreement with Central Piedmont Community College to serve as a facility for clinical rotations for nursing students. The project analyst notes that Exhibit M-1 does not contain a copy of an agreement between Metrolina Kidney Center and Central Piedmont Community College. However, Exhibit M-1 does contain a letter from Fresenius to South Piedmont Community College offering the Metrolina Kidney Center facility to be included in South Piedmont Community College list of facilities for clinical rotation of its nursing students.

The information provided in Section M.1 and Exhibit M-1 is reasonable and credible and supports a finding of conformity to this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.

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

C

BMA proposes to add five dialysis stations for a total of 16 certified dialysis stations and develop a home training program at the Metrolina Kidney Center following completion of this project and Project I.D. # F-11208-16 (relocate ten dialysis stations from Metrolina Kidney Center to develop a new ten station facility).

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

The July 2016 SDR indicates there are three dialysis facilities in Union County, as follows:

**Union County Dialysis Facilities
December 31, 2015**

Dialysis Facilities	Owner	# of Patients	Location	# of Certified Stations	# of Approved Stations	Percent Utilization
Marshville Dialysis	DVA	31	Marshville	12	0	64.58%
Metrolina Kidney Center	BMA	75	Monroe	21	0	89.29%
Union County Dialysis	DVA	92	Monroe	28	0	82.14%

As shown in the table above two of the three facilities in Union County are operated by DVA. Based on the most recent SDR, two of the three facilities operated in Union County operated at 80.0% utilization or above.

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

“The applicant does not expect this proposal to have effect on the competitive climate in Union County. The applicant does not project to serve dialysis patients currently being served by another provider. The projected patient population for the [Metrolina Kidney Center] facility begins with patients currently served by the facility, growth of that patient population, and a reflection of 37 patients to transfer care to FKC Indian Trail or FKC Southeast Mecklenburg County. BMA projects growth of the Union County ESRD patient population at a rate of 9.0% based upon the recent growth trends of the facility. There are three dialysis facilities within Union County. BMA seeks the opportunity to continue providing dialysis care and treatment to the patients of the area who are already choosing dialysis at a BMA facility.”

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

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

- The applicant adequately demonstrates the need for the proposed project and that it is an effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates that Metrolina Kidney Center will continue to provide quality dialysis services. The discussion regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- The applicant demonstrates that Metrolina Kidney Center will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (1), (3) and (13) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

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

C

In Section O, pages 65-67, and Exhibit O-1, the applicant discusses the methods it uses to ensure and maintain quality. In Section O, pages 63-67, the applicant lists three facilities that were cited for deficiencies that resulted in a finding of Immediate Jeopardy during the 18-month look back period: BMA Lumberton, BMA East Charlotte and RAI West College. See the table below which shows the survey dates and the dates the facilities were found to be back in compliance with CMS.

BMA QUALITY CARE		
FACILITY	SURVEY DATE	BACK IN COMPLIANCE
BMA Lumberton	5/6/2015	Yes
BMA East Charlotte	8/11/2015	Yes
RAI West College	3/15/2016	Yes

Based on a review of this certificate of need application and publicly available information, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. The application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

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

C

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The application is conforming or conditionally conforming to all applicable criteria, as 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- This application is to add stations and does not proposed establishing a new End Stage Renal Disease 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, pages 18-20, the applicant demonstrates that Metrolina Kidney Center will serve a total of 56 in-center patients at the end of Operating Year One for a utilization rate of 87.5% or 3.5 patients per station per week (56 patients / 16 stations = 3.5 / 4 =

.875 or 87.5%). 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 C.1, pages 18-20, 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.