

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: November 10, 2016

Findings Date: November 10, 2016

Project Analyst: Tanya S. Rupp

Team Leader: Fatimah Wilson

Project ID #: F-11208-16

Facility: Fresenius Kidney Care Indian Trail

FID #: 160339

County: Union

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

Project: Develop a new 10-station dialysis facility by relocating 10 existing stations from Metrolina Kidney Center

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. (BMA) (the “applicant”) proposes to develop a new 10-station dialysis facility, Fresenius Kidney Care Indian Trail (FKC Indian Trail), by relocating 10 existing certified dialysis stations from Metrolina Kidney Center (MKC), which the applicant also refers to as BMA Monroe. Both facilities are located in Union County. The applicant does not propose to add dialysis stations to an existing facility or to establish any new dialysis stations. Upon completion of this project and Project I.D.# F-11242-16, FKC Indian Trail will be certified for 10 dialysis stations and Metrolina Kidney Center will be certified for 16 dialysis stations [21 -10 + 5 = 16].

Need Determination

The applicant proposes to relocate existing dialysis stations within Union County; therefore, there are no need methodologies in the 2016 State Medical Facilities Plan (2016 SMFP) that are applicable to this review.

Policies

POLICY GEN-3: BASIC PRINCIPLES on page 39 of the 2016 SMFP is not applicable to this review because neither the county nor facility need methodology is applicable to this review.

POLICY GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES on page 39 of the 2016 SMFP is not applicable to this review because the applicant does not propose a capital expenditure greater than \$2 million.

However, *POLICY ESRD-2: RELOCATION OF DIALYSIS STATIONS* on page 33 of the 2016 SMFP is applicable to this review.

POLICY ESRD-2: RELOCATION OF DIALYSIS STATIONS states:

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

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

The applicant proposes to develop a new 10-station dialysis facility, FKC Indian Trail, in Union County, by relocating 10 existing Union County dialysis stations from Metrolina Kidney Center. Because both facilities are located in Union County, there will be no change in the total dialysis station inventory in Union County. Therefore, the application is consistent with Policy ESRD-2.

Conclusion

In summary, the applicant adequately demonstrates that the application is consistent with Policy ESRD-2 in the 2016 SMFP. 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 develop FKC Indian Trail, a new 10-station Union County dialysis facility, by relocating 10 existing certified dialysis stations from Metrolina Kidney Center, also in Union County. Throughout the application, the applicant refers to Metrolina Kidney Center as BMA Monroe; however, except where the applicant is quoted, the Findings refer to the facility as Metrolina Kidney Center (MKC), in accordance with the January 2016 North Carolina Semiannual Dialysis Report (SDR). The applicant does not propose to add dialysis stations to an existing facility or to establish any new dialysis stations. Upon completion of this project and Project I.D. #F-11242-16, FKC Indian Trail will be certified for 10 dialysis stations and Metrolina Kidney Center will be certified for 16 dialysis stations [21 – 10 + 5 = 16].

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 Union County. Facilities may serve residents of counties not included in their service area.

FKC Indian Trail will be a new facility in Union County; therefore, it has no existing patient origin.

In Section C.1, page 18, the applicant provides the projected patient origin for FKC Indian Trail for in-center (IC) dialysis patients for the first two years of operation following completion of the project, CY 2018 and CY 2019, as follows:

COUNTY	OY 1	OY 2	COUNTY PATIENTS AS % OF TOTAL	
	IN-CTR. PTS.	IN CTR. PTS.	OY 1	OY 2
Union	27.9	30.0	84.8%	85.7%
Mecklenburg	5.0	5.0	15.2%	14.3%
Total*	32.0	35.0	100.0%	100.0%

*Rounded down to the whole patient

The applicant provides the assumptions and methodology used to project patient origin in Section C-1, pages 18 - 19.

The applicant adequately identifies the population to be served.

Analysis of Need

In Section C.2, page 20, the applicant discusses the need to develop a new 10-station dialysis facility, FKC Indian Trail, by relocating 10 stations from Metrolina Kidney Center.

The applicant states that the location at which the patients who signed letters of support currently receive dialysis treatment is not as convenient for the patients, requires more time for travel to and from treatments, and involves more expense related to travel than the proposed location in Union County.

In Section C.1 – C.2, pages 18 - 20, the applicant provides the methodology and assumptions it used to project utilization. The assumptions are briefly discussed below:

1. The applicant plotted the residence location of patients dialyzing at BMA facilities within Union and Mecklenburg counties, which are contiguous. The applicant found that a significant number of BMA dialysis patients reside in the general area of Indian Trail. Exhibit C-1 includes letters from 32 in-center patients who state they reside in close proximity to the Indian Trail area and/or could be better served by a facility at the proposed location. The letters confirm the patients’ willingness to transfer care to the proposed facility.
2. The applicant projects 31 in-center patients who signed letters will transfer their care to the new facility.
3. The project is scheduled for completion on December 31, 2017.

Operating Year 1 is Calendar Year 2018, January 1 through December 31, 2018.
 Operating Year 2 is Calendar Year 2019, January 1 through December 31, 2019.

4. The applicant assumes the Union County dialysis patients transferring to the new FKC Indian Trail facility are a part of the Union County ESRD patient population as a whole, and that this population will increase at the Union County Five Year Average Annual Change Rate (AACR) of 7.4%, as published in the January 2016 SDR. The applicant state there are five patients from Mecklenburg County who are added to the census in

a separate step, rather than included in the Union County population. Therefore, the applicant begins with 26 Union County patients to begin growth projections.

Projected Utilization

The applicant's methodology, from page 19 of the application, is illustrated in the following table:

Begin with 26 Union County ESRD patients projected to transfer to the new facility as of 12/31/2017	26
Project this population forward using the Union County Five Year AACR of 7.4% to 12/31/2018	$26 \times 1.074 = 27.9$
Add the five Mecklenburg County residents who indicate in letters that they will transfer their care to the proposed facility	$27.9 + 5 = 32.9$
Project the Union County population forward using the Union County Five Year AACR of 7.4% to 12/31/2019	$27.9 \times 1.074 = 30.0$
Add the five Mecklenburg County residents who indicate in letters that they will transfer their care to the proposed facility	$30.0 + 5 = 35.0$

The applicant projects to serve 33 in-center patients or 3.3 patients per station per week ($33 / 10 = 3.3$) by the end of Operating Year 1 and 35 in-center patients or 3.5 patients per station per week ($35 / 10 = 3.5$) by the end of Operating Year 2 for the proposed 10-station facility. This satisfies 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 this application, the applicant assumes a projected annual rate of growth of 7.4% for the Union County dialysis patient census, which is consistent with the Union County Five Year Average Annual Change Rate (2010 - 2014). Projected utilization of the proposed dialysis facility is based on reasonable and adequately supported assumptions regarding continued growth at the facility.

Access to Services

In Section C.3, page 21, the applicant states that BMA and its parent company, Fresenius Medical Care Holdings, Inc. currently operates over 100 facilities in 42 North Carolina Counties. Each one has a patient population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, or other traditionally underserved persons. Form C, on page 85 of the application, shows that the applicant projects that 77.8% of the projected in-center patients will have some or all of their services paid for by Medicare or Medicaid. In Section C.3, page 21, the applicant states that low income persons will continue to have access to all services provided by Fresenius related facilities. In Section L.1(b), page 64, the applicant states its projections are based on the experience at MKC.

The applicant adequately demonstrates the extent to which all residents of the area, including the medically underserved, will have access to the proposed services.

Conclusion

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

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

C

The applicant proposes to develop FKC Indian Trail, a new 10-station Union County dialysis facility, by relocating 10 existing certified dialysis stations from Metrolina Kidney Center, also in Union County. Throughout the application, the applicant refers to Metrolina Kidney Center as BMA Monroe; however, except where the applicant is quoted, the Findings refer to the facility as Metrolina Kidney Center (MKC), in accordance with the January 2016 North Carolina Semiannual Dialysis Report (SDR). The applicant does not propose to add dialysis stations to an existing facility or to establish any new dialysis stations. Upon completion of this project and Project ID #F-11242-16, FKC Indian Trail will be certified for 10 dialysis stations and Metrolina Kidney Center will be certified for 16 dialysis stations [21 – 10 + 5 = 16].

In Section D.1, on pages 29 - 32, the applicant discusses how the needs of dialysis patients at Metrolina Kidney Center will continue to be met after the relocation of 10 stations to the proposed FKC Indian Trail dialysis facility. In Section D.1, page 29, the applicant projects that 26 patients will transfer their care to the proposed FKC Indian Trail from MKC. In Section C.1, page 19 of the application, the applicant assumes that the Union County dialysis patients who will transfer to the new FKC Indian Trail facility are a part of the Union County ESRD patient population as a whole, rather than all being transfers from the facility that is relocating stations.

The applicant also filed another application, Project ID # F-11207-16, in which the applicant projects that 11 patients currently dialyzing at MKC would also transfer their care to another proposed facility, FKC Southeast Mecklenburg County. The proposed certification date for both applications is December 31, 2017. Therefore, upon completion of both projects, the applicant projects the following utilization for MKC based on the Five Year Average Annual Change Rate (AACR) for Union County as published in the July 2016 Semi-Annual Dialysis Report (SDR):

BMA begins with the Union County ESRD patient population of MKC as of 12/31/15.	72
Project forward for 12 months to 12/31/16, using the Union County Five Year AACR.	$72 \times 1.074 = 77.3$
Project forward 12 months to 12/31/17.	$77.3 \times 1.074 = 83.1$
Subtract the 26 Union County patients to transfer to FKC Indian Trail and the 11 patients to transfer to FKC Southeast Mecklenburg County.	$83.1 - 37 = 46.1$
Add the patients from other counties. This is the projected census for 12/31/17.	$46.1 + 3 = 49.1$

Thus, as of December 31, 2017, following the relocation of stations and transfer of patients, Metrolina Kidney Center is projected to have 49 patients and 11 stations, which is a utilization rate of 111% ($49 \text{ patients} / 11 \text{ stations} = 4.45$; $4.45 / 4 = 1.1136$).

In Section C.12, page 27, the applicant states it intends to file a CON additional application to add additional stations to MKC. The applicant submitted an application, Project ID #F-11242-16, which seeks to add five stations to MKC for a total of 16 dialysis stations pursuant to the facility need methodology, for the Certificate of Need (CON) Review Cycle beginning October 1, 2016.

The applicant demonstrates that the needs of the population presently served at Metrolina Kidney Center will continue to be adequately met following the proposed relocation of ten dialysis stations and transfer of 26 patients from MKC, even taking into account the additional 11 patients projected to transfer their care from MKC as proposed in Project ID # F-11207-16.

Conclusion

The applicant adequately demonstrates that the needs of the population presently served will continue to be adequately met following the proposed relocation of ten existing certified dialysis stations from MKC to the proposed FKC Indian Trail.

Therefore, the application is conforming to this criterion.

- (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, pages 33 - 34, the applicant describes the alternatives it considered prior to submitting this application for the proposed project, which include:

- Maintain the status quo – The applicant states that maintaining the status quo is not an effective alternative due to the projected future ESRD patient population of Union County within its facility. Metrolina Kidney Center is currently at physical plant capacity and cannot be further expanded, although as a result of its utilization it would qualify pursuant to the Facility Need Methodology for an additional nine dialysis stations. Therefore, this alternative was rejected.

- Develop a facility in another area of Union County – The applicant states that evaluation of the existing patient populations served by BMA, and projections of future patient populations, indicate that the patient population in the Indian Trail area might be better served by a new facility. Therefore, this alternative was rejected.
- Develop a larger facility – The applicant states it considered a larger facility, but Metrolina Kidney Center could not lose more than 11 existing stations, because the relocation of 11 stations leaves that facility with ten stations, which is the minimum number of dialysis stations for a facility, in order to meet the minimum performance threshold at 10A NCAC 14C .2203.

After considering the above alternatives, the applicant states that, given the residence location of the existing patients projected to be served and the physical plant capacity issues, the project represented in this 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 Fresenius Kidney Care Indian Trail shall materially comply with all representations made in the certificate of need application.**
 - 2. Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Kidney Care Indian Trail shall relocate no more than 10 dialysis stations from Metrolina Kidney Center.**
 - 3. Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Kidney Care Indian Trail shall install plumbing and electrical wiring through the walls for no more than 10 dialysis stations, which shall include any isolation or home hemodialysis stations.**
 - 4. Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify 10 dialysis stations at Metrolina Kidney Center.**
 - 5. Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Kidney Care Indian Trail 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, Bio-Medical Applications of North Carolina Inc., proposes to develop a new 10-station Union County dialysis facility by relocating ten existing certified stations from Metrolina Kidney Center.

Capital and Working Capital Costs

In Section F.1, page 36, the applicant projects \$1,576,975 in capital costs to develop the proposed project. In Sections F.10 - F.12, pages 39 - 40, the applicant projects \$119,779 in start-up expenses and \$1,211,962 in initial operating expenses, for a total estimated working capital of \$1,331,741.

Availability of Funds

In Section F.2, page 37, and Section F.13, page 41, the applicant states it will finance the capital costs and working capital costs with the accumulated reserves of Bio-Medical Applications of North Carolina, Inc.

Exhibit F-1 contains a letter dated July 15, 2016, from the Senior Vice President & Treasurer for Fresenius Medical Care Holdings, Inc. (FMCH), as the parent company of BMA and also as the guarantor of the funds on behalf of FKC Indian Trail, which confirms availability and commitment of sufficient cash reserves for the capital costs of \$1,576,975, as well as, “*any additional funds as may be necessary for start-up costs in the new location.*” Exhibit F-2 contains the Consolidated Financial Statements for FMCH which indicates that it had \$249.3 million in cash and cash equivalents, \$19,332,534 in total assets and \$10,144,288 in net assets (total assets less total liabilities) as of December 31, 2015. The applicant adequately demonstrates that sufficient funds will be available for the capital and working capital needs of the project.

Financial Feasibility

In Section R, the applicant provides pro forma financial statements for the first two years of the project. In the pro forma financial statements (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.

	CY 2018	CY 2019
Total Net Revenue	\$2,339,768	\$2,485,819
Total Operating Expenses	\$1,817,943	\$1,906,480
Net Income	\$ 521,825	\$ 579,338

Source: application page 84; totals may not foot due to rounding

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section R, the financial section of the application, for the assumptions used regarding costs and charges. The discussion regarding utilization projections found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Conclusion

In summary, the applicant adequately demonstrates that sufficient funds will be available for the capital and working capital 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

The applicant proposes to develop FKC Indian Trail, a new 10-station Union County dialysis facility, by relocating ten existing certified dialysis stations from Metrolina Kidney Center, also in Union County. Throughout the application, the applicant refers to Metrolina Kidney Center as BMA Monroe; however, except where the applicant is quoted, the Findings refer to the facility as Metrolina Kidney Center (MKC), in accordance with the January 2016 North Carolina Semiannual Dialysis Report (SDR). The applicant does not propose to add dialysis stations to an existing facility or to establish any new dialysis stations. Upon completion of this project and Project ID #F-11242-16, FKC Indian Trail will be certified for 10 dialysis stations and Metrolina Kidney Center will be certified for 16 dialysis stations [21 – 10 + 5 = 16].

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 Union County. Facilities may serve residents of counties not included in their service area.

The July 2016 Semi Annual Dialysis Report shows three dialysis facilities are currently operating in Union County. The applicant operates one other dialysis facility; and DVA Healthcare Renal Care, Inc. (DVA), the only other provider of dialysis services in Union County, operates two dialysis centers, as shown in the table below.

Union County Dialysis Facilities and Utilization as of December 31, 2015

FACILITY	PROVIDER	# STATIONS AS OF 12/31/15	# IN- CENTER PATIENTS	# PATIENTS / STATION	% UTILIZATION
Marshville Dialysis Center	DVA	12	31	2.6	64.6%

Metrolina Kidney Center*	BMA	21	75	3.6	89.3%
Union County Dialysis	DVA	28	92	3.3	82.1%

Source: July 2016 Semi-Annual Dialysis Report, Table A

*This facility will be donating 10 stations pursuant to this application.

As shown in the table above, two of the three Union County dialysis facilities were operating above 80% utilization (3.2 patients per station) as of December 31, 2015. In Exhibit C-1, the applicant provides 32 signed letters of support from patients who currently dialyze at a BMA facility. Each letter states the proposed FKC Indian Trail facility would be a more convenient location for the patient, and that each patient would consider transferring care to the proposed facility.

The applicant does not propose to increase the number of dialysis stations in Union County as a result of this application; rather, it proposes to relocate existing stations to better serve a patient population that lives closer to the proposed location of FKC Indian Trail. Therefore, it is not duplicating services; rather, it is proposing to create a new facility to better serve existing patients using existing stations. Furthermore, the applicant provides reasonable projections for the patient population they propose to serve in Section C, pages 18 - 20 of the application. Growth projections for the patient population are based on the Union County Five Year AACR of 7.4% as published in the July 2016 SDR.

The applicant adequately demonstrates the need to relocate existing stations to develop a new 10-station dialysis facility in Union County. The discussion of need found in Criterion (3) is incorporated herein by reference. The discussion on the needs of the population presently served at Metrolina Kidney Center, found in Criterion (3a), is incorporated herein by reference.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved dialysis stations 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 47, the applicant provides the proposed staffing for the new facility, which includes 9.11 full-time equivalent (FTE) employee positions, as shown below.

POSITION	# FTEs
Registered Nurse	1.50
Patient Care Technician	4.00
Clinical Manager	1.00
Administrator	0.15
Dietician	0.33
Social Worker	0.33
Chief Technician	0.15
Equipment Technician	0.50
In-Service	0.15

Clerical	1.00
Total	9.11

Source: Page 47 of the application

In Section H.3, page 48 the applicant describes its experience and process for recruiting and retaining staff. On page 47, the applicant state the Medical Director is a contract position and not a direct employee of the facility.

In Section H.7, page 50, the applicant provides the projected Direct Care Staff Hours for Operating Year 2 for the proposed facility, as follows:

DIRECT CARE POSITIONS	# FTES	HOURS / YEAR / FTE	TOTAL ANNUAL FTE HOURS	TOTAL ANNUAL HOURS OF OPERATION	FTE HOURS / HOURS OF OPERATION
RN	1.50	2,080	3,120	3,120	1.00
Patient Care Tech	4.00	2,080	8,320	3,120	2.67
Total	5.50	4,160	11,440	3,120	3.67

Exhibit I-6 contains a copy of a letter dated June 27, 2016 from George M. Hart, M.D., expressing his commitment to serve as the Medical Director for the facility.

The applicant documents the availability of adequate health manpower and management personnel, including a Medical Director, to provide 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.1, page 51, the applicant provides a list of providers of the necessary ancillary and support services. Exhibits I-3, 4 and 5 contain documentation for laboratory, hospital and transplant services, respectively. Exhibit I-6 contains a letter from the proposed medical director of the facility expressing his support for the proposed project. In Sections I.3 and I.4, pages 52 - 54, the applicant discusses coordination with the existing health care system. 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.

C

In Section K.2, page 58, the applicant states it proposes to construct 2,927 square feet of new space in a leased building for the proposed dialysis facility. In Section F.1, page 36, the applicant lists the project costs, including \$1,003,409 for construction, \$573,566 in miscellaneous costs including water treatment equipment, furniture, architect/engineering fees, and a contingency for a total project cost of \$1,576,975. In Section K.1, pages 56 - 58, the applicant describes its plans for energy-efficiency and water conservation in the proposed facility. Costs and charges are described by the applicant in Section R of the application, beginning on page 80. 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.1, page 63, the applicant states that BMA has a long history of providing dialysis services to the underserved populations of North Carolina. FMC, BMA's parent company, currently operates 102 facilities in 42 North Carolina Counties, including affiliations with RRI facilities. The applicant further states its policy is 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 which would classify a patient as underserved.

In Section L.7, page 67, the applicant provides the historical payor mix for Metrolina Kidney Center, the facility that will donate stations, for CY 2015, as shown in the following table:

**Metrolina Kidney Center Payor Mix
CY 2015**

PAYOR TYPE	% OF PATIENTS
Private Pay	9.82%
Commercial Insurance	7.38%
Medicare	64.4%
Medicaid	7.36%
Misc. (includes VA)	5.02%
Other Medicare Commercial	6.02%
Total	100.0%

Totals may not foot due to rounding

As illustrated in the table above, 77.78% of Metrolina Kidney Center's patients were Medicare or Medicaid recipients in CY 2015. The facility proposed in this application is a new facility and has no current payor mix to report.

The applicant does not propose to provide home training at the proposed facility.

In addition, the applicant describes its admission and financial policies in Section L.3, pages 65 – 66, and provides a copy of its admission policy in Exhibit L-1, which states that patients will be admitted “*without regard to race, creed or religion, color, age, sex, disability, national origin, and or sexual orientation.*”

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 applicants' service area.

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2014 Estimate	2014 Estimate	2014 Estimate	2014 Estimate	2010-2014	2010-2014	2014 Estimate
Union	11%	51%	27%	11%	6%	16%
Statewide	15%	51%	36%	17%	10%	15%

<http://www.census.gov/quickfacts/table> Latest Data as of 12/22/15

*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."

However, a direct comparison to the applicant's current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities, women or handicapped persons utilizing health services.

The *Southeastern Kidney Council Network 6 Inc. Annual Report*¹ 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%

¹<http://www.esrdnetwork6.org/utills/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

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(e), page 66, 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 67, the applicant states there have been no civil rights access complaints filed against any BMA North Carolina facilities within 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, page 64, the applicant projects that 77.8% of the in-center patients who will receive treatments at FKC Indian Trail will have some or all of their services paid for by Medicare or Medicaid. The table below shows the projected (CY 2019) payor mix for the facility for in-center patients:

PAYOR TYPE	IN-CENTER PATIENTS
Self Pay/Indigent/Charity	9.82%
Medicare	64.40%
Medicaid	7.36%
Commercial Insurance	7.38%
Medicare/Commercial Insurance	6.02%
VA	5.02%
Total	100.00%

Totals may not foot due to rounding

In Section L, pages 63 - 65, the applicant provides the assumptions used to project payor mix. The applicant's projected payor mix in Section L are consistent with the facility's projected (CY 2019) payor mix as reported by the applicant in Section R, page 85. The applicant demonstrates that medically underserved groups will have

adequate access to the services offered at FKC Indian Trail. 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 66, the applicant describes the range of means by which a person will have access to the dialysis services at FKC Indian Trail, including referrals from 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 68, the applicant states that BMA facilities routinely work with local community training programs and students, and that the proposed facility will also offer the same opportunities to local health professional training programs. Exhibit M-1 contains a copy of correspondence to Central Piedmont Community College's professional training program expressing an interest on the part of the applicant to offer the proposed facility as a clinical training site. 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 proposes to develop FKC Indian Trail, a new 10-station Union County dialysis facility, by relocating ten existing certified dialysis stations from Metrolina Kidney Center, also in Union County. Throughout the application, the applicant refers to Metrolina Kidney Center as BMA Monroe; however, except where the applicant is quoted, the Findings refer to the facility as Metrolina Kidney Center (MKC), in accordance with the January 2016 North Carolina Semiannual Dialysis Report (SDR). The applicant does not propose to add dialysis stations to an existing facility or to establish any new dialysis stations. Upon completion of this project and Project ID #F-11242-16, FKC Indian Trail will be certified for 10 dialysis stations and Metrolina Kidney Center will be certified for 16 dialysis stations [21 – 10 + 5 = 16].

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 Union County. Facilities may serve residents of counties not included in their service area.

The July 2016 Semi Annual Dialysis Report shows three dialysis facilities are currently operating in Union County. The applicant operates one other dialysis facility; and DVA Healthcare Renal Care, Inc. (DVA), the only other provider of dialysis services in Union County, operates two dialysis centers, as shown in the table below.

Union County Dialysis Facilities and Utilization as of December 31, 2015

FACILITY	PROVIDER	# STATIONS AS OF 12/31/15	# IN-CENTER PATIENTS	# PATIENTS / STATION	% UTILIZATION
Marshville Dialysis Center	DVA	12	31	2.6	64.6%
Metrolina Kidney Center*	BMA	21	75	3.6	89.3%
Union County Dialysis	DVA	28	92	3.3	82.1%

Source: July 2016 Semi-Annual Dialysis Report, Table A

*This facility will be donating 10 stations pursuant to this application.

As shown in the table above, two of the three Union County dialysis facilities were operating above 80% utilization (3.2 patients per station) as of December 31, 2016. The applicant provides letters of support in Exhibit C-1 the applicant provides 32 signed letters of support from patients who currently dialyze at a BMA facility. Each letter states the proposed FKC Indian Trail facility would be a more convenient location for the patient, and that each patient would consider transferring care to the proposed facility.

The applicant does not propose to increase the number of dialysis stations in Union County as a result of this application; rather, it proposes to relocate existing stations to better serve a patient population that lives closer to the proposed location of FKC Indian Trail. Therefore, it is not duplicating services; rather, it is proposing to create a new facility to better serve existing patients using existing stations. Furthermore, the applicant provides reasonable projections for the patient population they propose to serve in Section C, pages 18 - 20 of the application. Growth projections for the patient population are based on the Union County Five Year AACR of 7.4% as published in the July 2016 SDR.

In Section N.1, pages 69 - 70, the applicant states it does not anticipate that this project will have any effect on competition in the area. The applicant discusses how the project 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 86% of the In-center treatments will be reimbursed at government payors (Medicare / Medicaid / VA) rates. 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, D, E, F, G, I, K, L, N, and O where the applicant discusses the impact of the project on the cost-effectiveness of the project and the quality of and access to services.

The information in the application is reasonable and adequately demonstrates that any enhanced competition in the service area would have a positive impact on the cost-effectiveness, quality and access to the proposed dialysis 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, including projected utilization, and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates that it will provide quality dialysis services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicant demonstrates that it will provide adequate access to dialysis services to medically underserved populations. The discussions regarding access found in Criteria (3) and (13) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

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

C

In Exhibit A-4, the applicant identifies the kidney disease treatment centers located in North Carolina owned and operated by BMA or an affiliated company. In Section O.3, pages 74 -

76, the applicant identifies three of its 102 Fresenius affiliated North Carolina facilities, BMA Lumberton, BMA East Charlotte and RAI West College - Warsaw, as having been 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. On page 76, the applicant states 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 BMA 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 to 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.*
- C- In Section C, the applicant adequately demonstrates the need to establish the proposed 10-station FKC Indian Trail dialysis facility by relocating 10 existing dialysis stations from an existing facility in Union County to the proposed facility, also in Union County. At the end of the first operating year, the applicant projects FKC Indian Trail will serve 33 in-center patients for a utilization of 3.3 patients per station per week. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.
- .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.

- NA- The applicant does not propose 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. The applicant proposes to develop a new 10-station dialysis facility.
- .2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section C.1, pages 18 - 19, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.