

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: April 12, 2017

Findings Date: April 12, 2017

Project Analyst: Tanya S. Rupp

Team Leader: Lisa Pittman

Project ID #: G-11287-17

Facility: Northwest Greensboro Kidney Center

FID #: 990214

County: Guilford

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

Project: Relocate four dialysis stations from BMA of Southwest Greensboro to Northwest Greensboro Kidney Center for a total of 37 stations at Northwest Greensboro Kidney Center upon project completion

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

The applicant, Bio-Medical Applications of North Carolina, Inc. d/b/a Northwest Greensboro Kidney Center (“BMA Northwest Greensboro”) proposes to relocate four dialysis stations from BMA of Southwest Greensboro (“BMA Southwest Greensboro”) to the existing facility for a total of 37 in-center dialysis stations upon completion of this project.

Need Determination

The applicant proposes to relocate existing dialysis stations within Guilford County; therefore, there are no need methodologies in the 2017 State Medical Facilities Plan (2017 SMFP) that are applicable to this review.

Policies

POLICY GEN-3: BASIC PRINCIPLES on page 33 of the 2017 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 33 of the 2017 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 27 of the 2017 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 county is currently serving residents of that contiguous county; and*
- 2. Demonstrate that the proposal shall not result in a deficit, or increase an existing deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*
- 3. Demonstrate that the proposal shall not result in a surplus, or increase an existing surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.”*

The applicant proposes to relocate four existing Guilford County dialysis stations from BMA Southwest Greensboro to BMA Northwest Greensboro. Because both facilities are located in Guilford County, there is no change in the total dialysis station inventory in Guilford County.

Conclusion

Therefore, the application is consistent with Policy ESRD-2.

- (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 relocate four dialysis stations from BMA Southwest Greensboro to BMA Northwest Greensboro for a total of 37 in-center dialysis stations at Northwest Greensboro Kidney Center upon project completion.

Patient Origin

On page 373, the 2017 SMFP defines the service area for dialysis services as “*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining North Carolina counties is a separate dialysis station planning area.*” Thus, the service area for this facility is Guilford County. Facilities may also serve residents of counties not included in their service area.

In Section C.8, page 21, the applicant provides the current (as of December 31, 2016) in-center patient origin for BMA Northwest Greensboro, as illustrated in the following table:

**BMA Northwest Greensboro Patient Origin
 December 31, 2016**

COUNTY	IN-CENTER PATIENTS
Guilford	96
Burke	1
Columbus	1
Forsyth	2
Rockingham	3
Stokes	1
South Carolina	2
Other States	1
Total	107

In Section C.1, page 17, the applicant projects in-center patient origin for BMA Northwest Greensboro for the first two years of operation following completion of the project, as shown in the table below.

BMA Northwest Greensboro Projected Patient Origin, CY 2018 – CY 2019

COUNTY	OY 1 (CY 2018)	OY 2 (CY 2019)	COUNTY PATIENTS AS % OF TOTAL	
	IN-CENTER PTS	IN-CENTER PTS	OY 1	OY 2
Guilford	113.2	117.7	95.0%	95.2%
Forsyth	2.0	2.0	1.7%	1.6%
Rockingham	3.0	3.0	2.5%	2.4%
Stokes	1.0	1.0	0.8%	0.8%
Total	119.2	123.7	100.0%	100.0%

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

Analysis of Need

In Section C.1, pages 17 – 18, the applicant provides the assumptions and methodology to support its need. The applicant’s assumptions and methodology are summarized below:

- The applicant assumes the BMA Northwest Greensboro patient population who are Guilford County residents will increase according to the Guilford County Five Year Average Annual Change Rate (AACR) of 4.0%.
- The applicant includes nine letters signed by existing BMA patients, each of which indicates the patient will consider transferring his or her care to the facility following the station relocation.
- The applicant projects the stations proposed in this application will be certified on December 31, 2017; therefore, the first project year is CY 2018 and the second project year is CY 2019.
- The applicant states there are 11 existing patients who are not residents of Guilford County, who will continue to dialyze at BMA Northwest Greensboro following project completion. Of those 11 patients, the applicant projects that six will remain at the facility. The applicant does not include those six patients to the facility growth projections, but adds them after calculating growth.

Projected Utilization

In Section C.1, page 18, the applicant begins with the Guilford County patient census as of December 31, 2016 (reported on the ESRD Data Collection Form), and projects the following utilization for BMA Northwest Greensboro following the relocation of the four stations from BMA Southwest Greensboro as proposed in this application:

Begin with Guilford County patients dialyzing at BMA Northwest Greensboro as of 12/31/16.	96
Project this population forward for one year to 12/31/17.	$96 \times 1.04 = 99.8$
Add the nine patients residing in Guilford County who are expected to transfer their care to the facility following the station relocation.	$99.8 + 9 = 108.8$
Add the six patients currently dialyzing at the facility from counties other than Guilford.	$108.8 + 6 = 114.8$
Project Guilford County patient census forward for one year to 12/31/18.	$108.8 \times 1.04 = 113.2$
Add the six patients currently dialyzing at the facility from counties other than Guilford.	$113.2 + 6 = 119.2$
Project Guilford County patient census forward for one year to 12/31/19.	$113.2 \times 1.04 = 117.7$
Add the six patients currently dialyzing at the facility from counties other than Guilford.	$117.7 + 6 = 123.7$

The applicant rounds down to the nearest whole number and projects to serve 119 in-center patients on 37 stations or 3.2 patients per station per week ($119 / 37 = 3.22$) by the end of

Operating Year 1, and 123 in-center patients or 3.32 patients per station per week ($123 / 37 = 3.32$) by the end of Operating Year 2 for the proposed facility. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

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

Access

In Section C.3, pages 19 - 20, the applicant states that BMA and its parent company, Fresenius Medical Care Holdings, Inc. currently operate 107 facilities in 46 North Carolina Counties. Each facility has a patient population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, or other traditionally underserved persons. In Section L.7, page 60, the applicant shows that in CY 2016, 89.41% of the in-center patients were recipients of Medicare or Medicaid. In Section L.1, page 57, the applicant projects the same percentage 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 19, the applicant states that it is corporate policy of Fresenius Medical Holdings, Inc. to provide dialysis services to all persons at all Fresenius related facilities.

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 relocate four dialysis stations from BMA Southwest Greensboro to BMA Northwest Greensboro for a total of 37 in-center dialysis stations at BMA Northwest Greensboro and 29 stations at BMA Southwest Greensboro upon project completion. Both facilities are located in Guilford County. The applicant does not propose to add new dialysis stations to an existing facility or to establish new dialysis stations in the county. Upon completion of this project, BMA Southwest Greensboro will be certified for 29 dialysis stations, and BMA Northwest Greensboro will be certified for 37 dialysis stations.

In Section D.1, pages 26 - 29, the applicant states that as of December 31, 2016, there were 113 in-center dialysis patients at BMA Southwest Greensboro dialyzing on 33 dialysis stations, for a utilization rate of 85.6% [$113 / 33 = 3.42$; $3.42 / 4 = 0.856$]. Of the 113 patients, the applicant states that 105 were residents of Guilford County, as shown in the following table:

BMA of Southwest Greensboro 12/31/16

COUNTY	# PATIENTS
Guilford	105
Davidson	3
Mecklenburg	1
Randolph	1
South Carolina	1
Other States	2
Total	113

The applicant proposes to relocate four stations from BMA Southwest Greensboro to BMA Northwest Greensboro. The applicant assumes that the number of Guilford County residents dialyzing at BMA Southwest Greensboro will increase at 4.0% per year based on the Five Year AACR for Guilford County, as reported in Table B of the January 2017 SDR. In Section D.1, page 27, the applicant calculates the in-center patient census for BMA Southwest Greensboro through December 31, 2017, the projected certification date for the relocated stations at BMA Northwest Greensboro, as illustrated in the following table:

Begin with Guilford County in-center patient census as of December 31, 2016	105
Project this census forward one year to December 31, 2017, using the Guilford County Five Year AACR	$105 \times 1.04 = 109.2$
Add the 8 patients from outside Guilford County who dialyze at the facility	$109.2 + 8 = 117.2$
Projected patient census for December 31, 2017, date of certification for stations relocating to BMA Northwest Greensboro	117

By the end of 2017, BMA Southwest Greensboro will have 117 in-center patients dialyzing on 29 stations, which is a utilization rate of 100.8%, or 4.03 patients per station per week [$117 / 29 = 4.03$; $4.03 / 4 = 1.008$].

The applicant states on page 29 that it will continue to make dialysis services available to all residents in the service area, stating that the relocation of stations will not affect the ability of underserved groups to obtain needed care at either dialysis facility.

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

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

CA

In Section E.1, page 30, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

- Maintain the Status Quo –The applicant states that maintaining the status quo is not an effective alternative because it ignores the needs of current patients who live close to BMA Northwest Greensboro, but because of capacity issues must travel to another BMA facility. The applicant states maintaining the status quo would not enhance access to dialysis care for patients who reside in Guilford County.
- Relocate Stations from another BMA facility – the applicant states this alternative is not effective because it must consider the opportunity to add stations back to the facility from which stations would be relocated. BMA Southwest Greensboro’s utilization actually generates a need for additional stations because of its utilization, but the facility lacks the physical capacity to add additional stations. Therefore, the applicant states the decision to relocate stations from that facility and then add them back is the most effective alternative.
- Develop a new 10-station dialysis facility in Guilford County – The applicant states that although it may apply later to split facilities in Guilford County to develop a new facility, the current proposal to relocate existing stations is the most expeditious method of serving the current Guilford County ESRD patient population.

After considering those alternatives, the applicant states the alternative represented in the application is the most effective alternative to meet the identified need.

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

In summary, the applicant adequately demonstrates that 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 Northwest Greensboro 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 Northwest Greensboro Kidney Center shall add no more than four dialysis stations for a total of 37 dialysis stations, which shall include any home hemodialysis or isolation stations, following project completion.**
3. **Bio-Medical Applications of North Carolina, Inc. d/b/a Northwest Greensboro Kidney Center shall install plumbing and electrical wiring through the walls**

for no more than five 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 four existing stations for a facility total of no more than 29 in-center dialysis stations upon completion of this project.**
 - 5. Bio-Medical Applications of North Carolina, Inc. d/b/a Northwest Greensboro 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

The applicant proposes to relocate four dialysis stations from BMA of Southwest Greensboro to the existing facility for a total of 37 in-center dialysis stations upon completion of this project.

Capital and Working Capital Costs

In Section F.1, page 33, the applicant projects \$15,000 in capital costs to develop the proposed project. In Sections F.10 - F.12, page 36, the applicant states there will be no start-up costs or initial operating expenses incurred for this project since the facility is currently operational; therefore, the total capital cost for the project is \$15,000.

Availability of Funds

In Section F.2, page 34, and Section F.13, page 37, the applicant states it will finance the capital costs with accumulated reserves of Fresenius Medical Care, Inc., as shown below.

Accumulated Reserves / Owner's Equity	
	TOTAL
Capital Costs	\$15,000

Exhibit F-1 contains a letter dated January 17, 2017, from the Senior Vice President & Treasurer for Fresenius Medical Care Holdings, Inc. (FMCH), as the parent company of BMA, which confirms authorization and commitment of the cash reserves for the full project capital costs. Exhibit F-2 contains the Consolidated Financial Statements for FMCH which indicates that it had \$249 million in cash and cash equivalents as of December 31, 2015. In addition, the balance sheets show a total of \$10,144,288 in net assets (total assets less total liabilities). 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 of the application and in clarifying information provided at the Agency’s request, 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.

	OPERATING YEAR 1 (CY 2018)	OPERATING YEAR 2 (CY 2019)
Total Treatments	17,339	17,933
Total Gross Revenues (Charges)	\$5,447,885	\$5,634,205
Total Net Revenue	\$5,121,012	\$5,296,153
Total Operating Expenses (Costs)	\$4,227,123	\$4,362,871
Net Income	\$893,889	\$933,282

Totals may not sum 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 relocate four dialysis stations from BMA Southwest Greensboro to BMA Northwest Greensboro for a total of 37 in-center dialysis stations at Northwest Greensboro Kidney Center and 29 in-center dialysis stations at BMA Southwest Greensboro upon project completion.

On page 373, the 2017 SMFP defines the service area for dialysis services as “the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining North Carolina counties is a separate dialysis station planning area.” Thus, the service area for this facility is Guilford County. Facilities may also serve residents of counties not included in their service area.

The January 2017 SDR indicates there are currently seven existing dialysis facilities and one approved dialysis facility in Guilford County, six of which are owned and operated by Bio-Medical Applications of North Carolina, Inc. or one of its affiliated companies. See the following table, which illustrates the existing and approved dialysis facilities and their utilization, taken from the January 2017 SDR:

BMA Guilford County Facilities and Utilization as of June 30, 2016

FACILITY	PROVIDER	# STATIONS	# PATIENTS	# PTS. / STATION	% UTILIZATION
BMA of Greensboro	BMA	56	179	3.20	79.9%
BMA of South Greensboro	BMA	59	181	3.07	76.7%
BMA of Southwest Greensboro	BMA	33	117	3.55	88.6%
FMC of East Greensboro	BMA	35	130	3.71	92.9%
Fresenius Medical Care High Point*	BMA	0	0	N/A	N/A
High Point Kidney Center	Wake Forest Baptist	42	153	3.64	91.1%
Northwest Greensboro Kidney Center	BMA	33	99	3.00	75.0%
Triad Dialysis Center	Wake Forest Baptist	22	83	3.77	94.3%
Total		280	942	3.36	84.1%

*In October 2015, BMA was approved to develop Fresenius Medical Care High Point, a new 10-station facility in Greensboro, to be operational later this year.

All of the existing BMA facilities in Guilford County were operating at least at 75% of capacity as of June 30, 2016. The other two dialysis facilities were operating above 90% of capacity during the same time. The utilization of dialysis facilities in Guilford County as a whole is 84.1%.

The applicant is not increasing the total number of dialysis stations in Guilford County; rather, it is transferring existing stations from one facility to another facility in order to more effectively serve existing patients.

The applicant adequately demonstrates the need to relocate four existing stations from BMA Southwest Greensboro to BMA Northwest Greensboro. The discussion on analysis of need found in Criterion (3) is incorporated herein by reference.

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

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In Section H.1, page 44, the applicant provides a staffing chart to illustrate proposed staffing following the development of the project. The applicant does not propose to add any full time equivalent (FTE) staff positions following the relocation of the four stations. See the following table, from page 44:

**BMA Northwest Greensboro
Current and Projected Staffing**

POSITION	TOTAL FTE POSITIONS
Registered Nurse	5.00
Patient Care Technician	12.00
Clinical Manager	1.00
Administrator	0.25
Dietician	1.00
Social Worker	1.00
Chief Technician	0.20
Equipment Technician	1.00
In-Service	0.30
Clerical	1.00
Total	22.75

In Section I.3, page 48, the applicant identifies Dr. Cynthia Dunham as the current and continuing Medical Director of the facility. In Exhibit I-5, the applicant provides a letter signed by Dr. Dunham, dated January 9, 2017, confirming her commitment to serve as Medical Director.

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.1, page 47, the applicant includes a list of providers of the necessary ancillary and support services for the patients who dialyze at the facility. In Exhibit I-1, I-2, I-3 and I-4, the applicant provides home training, lab, hospital affiliation and transplant agreements, respectively. In Section I-4, page 49, the applicant discusses the facility's relationship with local healthcare and social services providers. On page 49, the applicant provides a list of physicians who have expressed support for the project. The applicant adequately demonstrates that the necessary ancillary and support services will continue to be available and that the proposed

services will be continue to be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

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

NA

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

NA

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

NA

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

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

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In Section L.1, page 56, 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 107 facilities in 46 North Carolina Counties, including affiliations with RRI facilities. The applicant states there are several additional facilities under development. 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 60, the applicant provides the historical payor mix for both BMA Southwest Greensboro and BMA Northwest Greensboro for CY 2016, as shown in the following table:

BMA Payor Mix Percentage CY 2016

PAYMENT SOURCE	BMA SOUTHWEST GREENSBORO	BMA NORTHWEST GREENSBORO
Self-Pay / Indigent / Charity	1.90%	0.00%
Medicare	63.67%	63.36%
Commercial Insurance	7.49%	7.40%
Medicare / Commercial	17.30%	20.64%
Medicaid	4.76%	5.41%
Misc. (includes VA)	4.89%	3.18%
Total	100.00%	100.00%

Totals may not foot due to rounding

As illustrated in the table above, 85.73% of BMA Southwest Greensboro's patients were Medicare or Medicaid recipients, and 89.41% of BMA Northwest Greensboro's patients were Medicare or Medicaid recipients in CY 2016.

The applicant does not provide home training at BMA Northwest Greensboro.

In addition, the applicant describes its admission and financial policies in Section L.3, page 58, 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
Guilford	14%	53%	48%	17%	7%	18%
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 Report¹* 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%

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

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

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

C

In Section L.3(e), page 58, 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 59, 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(b), page 57, the applicant projects that 89.41% of the in-center patients who will receive treatments at BMA Northwest Greensboro will have some or all of their services paid for by Medicare or Medicaid. The table below shows the projected payor mix for the facility for in-center patients in PY 2 (CY 2019):

PAYMENT SOURCE	BMA NORTHWEST GREENSBORO
Self-Pay / Indigent / Charity	0.00%
Medicare	63.36%
Commercial Insurance	7.40%
Medicare / Commercial	20.64%
Medicaid	5.41%
Misc. (includes VA)	3.18%
Total	100.00%

Totals may not foot due to rounding

On page 57 the applicant states projected payor mix is based on the historical performance of BMA Northwest Greensboro. The applicant's projected payor mix in Section L is consistent with the facility's projected (CY 2019) payor mix as reported by the applicant in Section R, page 78. The applicant demonstrates that medically underserved groups will continue to have adequate access to the dialysis services offered at BMA Northwest Greensboro. 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 59, the applicant describes the range of means by which a person will have access to the dialysis services at BMA Northwest Greensboro, 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 61, the applicant states that it has communicated with the student nursing program at Guilford Technical Community College to offer the facility as a clinical training site for nursing students. In Exhibit M-1, the applicant provides a letter to Guilford Technical Community College that invites the college to include the facility in its clinical nursing rotation. 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 relocate four in-center dialysis stations from BMA Southwest Greensboro to BMA Northwest Greensboro for a total of 37 in-center dialysis stations at BMA Northwest Greensboro and 29 in-center dialysis stations at BMA Southwest Greensboro upon project completion.

On page 373, the 2017 SMFP defines the service area for dialysis services as “*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining North Carolina counties is a separate dialysis station planning area.*” Thus, the service area for this facility is Guilford County. Facilities may also serve residents of counties not included in their service area.

The January 2017 SDR indicates there are currently seven existing dialysis facilities and one approved dialysis facility in Guilford County, six of which are owned and operated by Bio-Medical Applications of North Carolina, Inc. or one of its affiliated companies. See the following table, which illustrates the existing and approved dialysis facilities and their utilization, taken from the January 2017 SDR:

BMA Guilford County Facilities and Utilization as of June 30, 2016

FACILITY	PROVIDER	# STATIONS	# PATIENTS	# PTS. / STATION	% UTILIZATION
BMA of Greensboro	BMA	56	179	3.20	79.9%
BMA of South Greensboro	BMA	59	181	3.07	76.7%
BMA of Southwest Greensboro	BMA	33	117	3.55	88.6%
FMC of East Greensboro	BMA	35	130	3.71	92.9%
Fresenius Medical Care High Point*	BMA	0	0	NA	NA
High Point Kidney Center	Wake Forest Baptist	42	153	3.64	91.1%
Northwest Greensboro Kidney Center	BMA	33	99	3.00	75.0%
Triad Dialysis Center	Wake Forest Baptist	22	83	3.77	94.3%
Total		280	942	3.36	84.1%

*In October 2015, BMA was approved to develop Fresenius Medical Care High Point, a new 10-station facility in Greensboro, to be operational later this year.

All of the existing BMA facilities in Guilford County were operating at least at 75% of capacity as of June 30, 2016. The other two dialysis facilities were operating above 90% of capacity during the same time. This is based on the assumption that dialysis facilities that operate four shifts per week (2 per day on alternate days) have a capacity of four patients per station per week. The utilization of dialysis facilities in Guilford County as a whole is 84.1%.

In Section N.1, page 62, the applicant discusses how any enhanced competition will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states:

“BMA does not expect this proposal to have effect on the competitive climate in Guilford County. According to the January 2017 SDR there are currently seven dialysis facilities operating within Guilford County. Five facilities are operated by BMA and two facilities are operated by Wake Forest Baptist Hospital. ... BMA seeks the opportunity to continue providing dialysis care and treatment to the patients of the area.

...

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 90% of the In-center patients will be relying upon government payors (Medicare/Medicaid/VA). 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 B, C, E, F, G, H and L in which the applicant discusses the impact of the project on cost-effectiveness, quality and access.

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

- The applicant adequately demonstrates the need to add four dialysis stations to the existing facility and that it is a cost-effective alternative. The discussions regarding the analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates it will provide quality services. The discussion regarding quality found in Criteria (1) and (20) is incorporated herein by reference.
- The applicant demonstrates that it will provide adequate access to medically underserved populations. The discussion regarding access found in Criteria (1), (3) and (13) is 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 the applicant or an affiliated company. In Section O.3, pages 67 - 68, the applicant identifies two of its North Carolina facilities, BMA East Charlotte and RAI West College-Warsaw Dialysis that were cited in the past 18 months for deficiencies in compliance with 42 CFR Part 494, the Centers for Medicare and Medicaid (CMS) Conditions for Coverage of ESRD facilities. On page 68, the applicant states both facilities are currently

back in full compliance with CMS Guidelines as of the date of submission of this application. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. The application is conforming to this criterion.

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

C

The application is conforming 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*
- NA- The applicant does not propose to establish a new End Stage Renal Disease facility.
- (b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*
- C- In Section C.1, page 17, the applicant projects the facility will dialyze 123 in-center patients on 37 stations in the first operating year, which is 3.32 patients per station per week.
- (c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*

- C- The applicant provides all assumptions, including the methodology by which patient utilization is projected, in Section C.1, pages 17 - 18.