

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 15, 2016

Findings Date: December 15, 2016

Project Analyst: Jane Rhoe-Jones

Team Leader: Lisa Pittman

Project ID #: L-11227-16

Facility: Rocky Mount Kidney Center

FID #: 944658

County: Nash

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

Project: Add three dialysis stations for a total of 40 stations upon completion of this project, Project I.D.# L-10177-13 (relocate 12 stations to FMC South Rocky Mount) and Project I.D.# L-10182-13 (add seven for a total of 37 stations)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications of North Carolina, Inc. d/b/a Rocky Mount Kidney Center, aka BMA of Rocky Mount, proposes to add three dialysis stations for a total of 40 certified dialysis stations upon completion of this project, Project I.D.# L-10177-13 (relocate 12 stations to FMC South Rocky Mount) and Project I.D.# L-10182-13 (add seven for a total of 37 stations is complete and was certified on August 10, 2016 – see Exhibit A-3 for a copy of the certification letter).

Need Determination

The 2016 State Medical Facilities Plan (2016 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2016 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of three dialysis stations in Nash County, thus the applicant cannot apply to add any additional stations based on the county need methodology. However, an applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. The applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate reported for Rocky Mount Kidney Center in the July 2016 SDR is 4.0 patients per station per week, or 100% (4.0000 / 4 patients per station = 1.0000). This utilization rate was calculated based on 168 in-center dialysis patients and 42 certified dialysis stations (168 patients / 42 stations = 4.0000 patients per station per week).

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

ROCKY MT KIDNEY CENTER ---OCTOBER 1 REVIEW-JULY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/15		100.0%
Certified Stations		42
Pending Stations		7
Total Existing and Pending Stations		49
In-Center Patients as of 12/31/15 (July 2016 SDR) (SDR2)		168
In-Center Patients as of 6/30/16 (Jan 2016 SDR) (SDR1)		169
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	-1
	Multiply the difference by 2 for the projected net in-center change	-2
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/14	-0.0118
(ii)	Divide the result of Step (i) by 12	-0.0010
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/13 until 12/31/14)	-0.0118
(iv)	Multiply the result of Step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	166.0118
(v)	Divide the result of Step (iv) by 3.2 patients per station	51.8787
	and subtract the number of certified and pending stations to determine the number of stations needed	2.8787

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is three stations. Step (C) of the facility need methodology states, “The facility may apply to expand to meet the need established ..., up to a maximum of

ten stations.” The applicant proposes to add three new stations, therefore the application is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2016 SMFP which is applicable to this review. *POLICY GEN-3: BASIC PRINCIPLES* on page 39 of the 2016 SMFP is applicable to this review because the facility need methodology is applicable to this review. Policy GEN-3 states:

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

Promote Safety and Quality

The applicant describes how it believes the proposed project would promote safety and quality in Section B, pages 12 and 14-15, and Section O, pages 56-61. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project would promote equitable access in Section B, page 13, Section C, page 20, Section I, pages 41-42, Section L, pages 49-53 and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project would maximize healthcare value in Section B, pages 14-16, Section N, page 55, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

Conclusion

In summary, the applicant adequately demonstrates that the proposal is consistent with the facility need methodology in the July 2016 SDR and Policy GEN-3. Therefore, the application is conforming to this criterion.

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

C

BMA proposes to add three dialysis stations for a total of 40 certified dialysis stations at the Rocky Mount Kidney Center, aka BMA of Rocky Mount, upon completion of this project, Project I.D.# L-10177-13 (relocate 12 stations to FMC South Rocky Mount) and Project I.D.# L-10182-13 (add seven for a total of 37 stations is complete and was certified on August 10, 2016 – see Exhibit A-3 for a copy of the certification letter). Rocky Mount Kidney Center provides both hemodialysis and peritoneal dialysis home therapy programs. However, this application is for additional in-center dialysis stations.

Patient Origin

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

In Section C, page 22, the applicant provides a table, as shown below with the historical patient origin for in-center (IC) patients, home hemodialysis and peritoneal dialysis patients served by Rocky Mount Kidney Center:

ROCKY MOUNT KIDNEY CENTER			
Dialysis Patients as of August 31, 2016*			
County	IC Patients	Home Hemodialysis Patients	Peritoneal Dialysis Patients
Nash	83	6	15
Edgecombe	19	3	4
Halifax	18	0	2
Northampton	0	1	0
Total	120	10	21

*As reported on the ESRD Data Collection Forms June 30, 2016.

In Section C, page 17, the applicant identifies the patient population it proposes to serve during the first two years of operation following project completion, as illustrated below in the table:

ROCKY MOUNT KIDNEY CENTER PROJECTED PATIENT POPULATON								
COUNTY	OPERATING YEAR 1			OPERATING YEAR 2			COUNTY PATIENTS AS % OF TOTAL	
	IC	PD	HH	IC	PD	HH	OY 1	OY 2
Nash	103.8	18.8	7.5	114.2	20.6	8.3	73.5%	75.3%
Edgecombe	19	4	3	19	4	3	14.7%	13.7%
Halifax	18	2	0	18	2	0	11.3%	10.5%
Northampton	0	0	1	0	0	1	0.6%	0.5%
Total	140.8	24.8	11.5	151.2	26.6	12.3	100.0%	100.0%

The applicant provides the assumptions and methodology for the projections above on pages 17-21.

The applicant adequately identifies the population it proposes to serve.

Analysis of Need

In Section C, pages 19-20, the applicant states the need for the proposed project is based on the following factors:

- ESRD patients require dialysis treatment on a regular and consistent basis in order to maintain life.
- Failure to add the proposed stations will lead to higher utilization rates at the existing facility.
- The need of the patient population projected to utilize the proposed service is a function of individual patient need for dialysis care and treatment.

Projected Utilization

In Section C, page 17, the applicant provides projected utilization during the first two years of operation following project completion, as illustrated below in the table:

ROCKY MOUNT KIDNEY CENTER PROJECTED PATIENT POPULATON								
COUNTY	OPERATING YEAR 1			OPERATING YEAR 2			COUNTY PATIENTS AS % OF TOTAL	
	IC	PD	HH	IC	PD	HH	OY 1	OY 2
Nash	103.8	18.8	7.5	114.2	20.6	8.3	73.5%	75.3%
Edgecombe	19	4	3	19	4	3	14.7%	13.7%
Halifax	18	2	0	18	2	0	11.3%	10.5%
Northampton	0	0	1	0	0	1	0.6%	0.5%
Total	140.8	24.8	11.5	151.2	26.6	12.3	100.0%	100.0%

In Section C, pages 17-18, the applicant provides the assumptions and methodology to project in-center utilization. The applicant utilizes the same assumptions for home hemodialysis and peritoneal dialysis, as for in-center utilization.

On page 18, the applicant provides a table illustrating how in-center utilization is projected, which is summarized below:

- Operating Year 1 = Calendar Year 2018
- Operating Year 2= Calendar Year 2019
- Growth rate of 10.0% for the patient population residing in Nash County which is the Five-Year Average Annual Growth Rate for Nash County, as published in the July 2016 SDR.
- No growth projected for patients from outside the service area (Nash County).

Application of the applicant’s assumptions and methodology for in-center dialysis patients are illustrated in the following table.

ROCKY MOUNT KIDNEY CENTER METHODOLOGY IN-CENTER DIALYSIS PROJECTIONS	
Begin with the Nash County patients dialyzing at Rocky Mount Kidney Center as of August 31, 2016.	83
Project the Nash County patient population forward 4 months to December 31, 2016.	$83 \times (.10 / 12 \times 4) + 83 = 85.8$
Project this patient population forward one year to December 31, 2017.	$(85.8 \times .10) + 85.8 = 94.4$
Add patients from other counties. This is the beginning census for OY1.	$94.4 + 37 = 131.4$
Project the Nash County patient population forward 12 months to December 31, 2018	$(94.4 \times .10) + 94.4 = 103.8$
OY1: Add patients from other counties. This is the ending census for OY1.	$103.8 + 37 = \mathbf{140.8}$
Project Nash County patient population forward one year to December 31, 2019.	$(103.8 \times .10) + 103.8 = 114.2$
OY2: Add patients from other counties. This is the ending census for OY2.	$114.2 + 37 = \mathbf{151.2}$

The applicant projects that Rocky Mount Kidney Center will serve a total of 140 in-center patients at the end of Operating Year One for a utilization rate of 87.5% or 3.5 patients per station (140 patients / 40 stations = 3.500 / 4 = .8750 or 87.5%). The projected utilization of 3.5 patients per station per week for Operating Year One satisfies the 3.2 in-center patients per station threshold as required by 10A NCAC 14C .2203(b).

Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth at Rocky Mount Kidney Center.

Access

In Section L, pages 49-50, the applicant states that each of BMA's 105 facilities in 42 North Carolina counties has a patient population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, or other underserved persons. The applicant projects 85.2% of its total patients and 88.1% of its in-center patients will be Medicare or Medicaid recipients in Project Year 2. The applicant adequately demonstrates the extent to which all residents of the service area, including underserved groups, are likely to have access to its services.

Conclusion

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

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

NA

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

CA

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

- Maintain the Status Quo –The applicant states that maintaining the status quo is not an effective alternative due to the lack of capacity at the facility to meet the need of patients choosing to dialyze at the Rocky Mount Kidney Center facility.
- Apply for Fewer Stations – The applicant states it considered applying for fewer than three stations but rejected the alternative because it would fail to meet the need based on the projected levels of utilization for Rocky Mount Kidney Center.

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 Rocky Mount 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 Rocky Mount Kidney Center shall develop and operate no more than three additional dialysis station at Rocky Mount Kidney Center for a total of no more than 40 certified dialysis stations upon completion of this project, Project I.D.# L-10177-13 (relocate 12 stations to FMC South Rocky Mount) and Project I.D.# L-10182-13 (add seven for a total of 37 stations is complete and was certified on August 10, 2016) which shall include any isolation or home hemodialysis training stations.**
 3. **Bio-Medical Applications of North Carolina, Inc. d/b/a Rocky Mount Kidney Center shall install plumbing and electrical wiring through the walls for no more than three additional dialysis stations, for a total of 40 stations upon completion of this project, Project I.D.# L-10177-13 (relocate 12 stations to FMC South Rocky Mount) and Project I.D.# L-10182-13 (add seven for a total of 37 stations is complete and was certified on August 10, 2016).**
 4. **Bio-Medical Applications of North Carolina, Inc. d/b/a Rocky Mount Kidney Center shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

BMA proposes to add three dialysis station for a total of 40 certified dialysis stations at the Rocky Mount Kidney Center facility upon completion of this project, Project I.D.# L-10177-13 (relocate 12 stations to FMC South Rocky Mount) and Project I.D.# L-10182-13 (add seven for a total of 37 stations is complete and was certified on August 10, 2016).

Capital and Working Capital Costs

In Section F, page 29, the applicant projects it will incur no capital costs for the proposed project, because the space already exists. In Section F, page 30, the applicant states that there are no working capital needs for the proposed project since Rocky Mount Kidney Center is an existing facility.

Financial Feasibility

In the projected revenue and expense statement in Section R, Form B, the applicant projects revenues will exceed operating expenses in the first two operating years following completion of the proposed project, as shown below in the table.

ROCKY MOUNT KIDNEY CENTER		
	CY2018	CY2019
Total Net Revenue	\$9,144,143	\$9,709,028
Total Operating Expenses	\$6,916,306	\$7,370,030
Net Income	\$2,227,838	\$2,338,998

The assumptions used by the applicant in preparation of the pro formas are reasonable and adequately supported, including the projected number of treatments. See the financial section of the application for the assumptions used regarding costs and charges. In Section, H.1, page 37, the applicant provides projected staffing and salaries. Form A in Section R, shows budgeted operating costs adequate to cover the projected staffing. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The discussion regarding staffing found in Criterion (7) is incorporated herein by reference. The applicant adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of costs and charges.

Conclusion

In summary, the applicant does not project any capital costs; however, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

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

C

BMA proposes to add three dialysis stations for a total of 40 certified dialysis stations at the Rocky Mount Kidney Center facility upon completion of this project. Project I.D.# L-10177-13 (relocate 12 stations to FMC South Rocky Mount) and Project I.D.# L-10182-13 (add seven for a total of 37 stations is complete and certified on August 10, 2016.

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

The applicant, BMA operates the two existing centers in Nash County. BMA has one facility approved, but not yet operational. DaVita has been approved for Nash County Dialysis; which

if developed would be the fourth dialysis center in Nash County. However, development of that facility is pending the outcome of an appeal. There are no other providers of dialysis services in Nash County.

NASH COUNTY DIALYSIS FACILITIES			
Dialysis Facility	Certified Stations 12/31/2015	% Utilization	Patients Per Station
Rocky Mount Kidney Center	42	100.00%	4.0000
FMC Spring Hope	15	85.00%	3.4000
FMC South Rocky Mount*	0*	00.00%	0.0000
Nash County Dialysis**	0**	00.00%	0.0000

Source: July 2016 SDR, Table A. *Con Issued for 12 stations 11/19/13. ** Con Issued for 12 stations 7/17/16.

As shown in the table above, based on the most recent SDR, the two existing dialysis facilities in Nash County were operating above 80% (3.2 patients per station).

In Section C, pages 17-19, the applicant projects that Rocky Mount Kidney Center will serve a total of 140 in-center patients at the end of Operating Year One for a utilization rate of 87.5% or 3.5 patients per station (140 patients / 40 stations = 3.500 / 4 = .8750 or 87.5%). According to the July 2016 SDR, there is a deficit of three dialysis stations in Nash County. Moreover, the applicant is applying to add three additional stations based on the facility need methodology

The applicant states that the projected utilization rates are based on patients currently dialyzing at Rocky Mount Kidney Center. The applicant adequately demonstrates the need to add three additional station at Rocky Mount Kidney Center based on the number of in-center patients it proposes to serve. The discussion on analysis of need found in Criterion (3) is incorporated herein by reference. The discussion on competition found in Criterion (18a) is incorporated herein by reference.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities in Nash County. Consequently, the application is conforming to this criterion.

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

C

In Section H.1, page 37, the applicant provides the current staffing for the facility, which includes 27.45 full-time equivalent (FTE) employees. The applicant projects to add 1.0 FTE Patient Care Tech which will total 13.00 FTE Patient Care Techs and 28.45 total FTEs following completion of the project. In Section H.3, page 38, the applicant describes its experience and process for recruiting and retaining staff, and states that it does not anticipate difficulties in hiring the required staff for this project. Exhibit I-5 contains a copy of a letter from Michael Holland, M.D., expressing his interest in continuing to serve as the Medical Director for the facility. The applicant adequately demonstrates the availability of sufficient

health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section I, page 40, the applicant includes a list of providers of the necessary ancillary and support services. Exhibit I-5 contains a letter from the medical director of the facility expressing his support for the proposed project. The applicant discusses coordination with the existing health care system on page 42. Exhibits I-3 through I-5, respectively, contain copies of agreements. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

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

NA

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

NA

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

other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

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

C

In Section L, page 49, the applicant states that BMA has a long history of providing dialysis services to underserved populations in North Carolina. FMC, BMAs parent company, currently operates 105 facilities in 42 North Carolina counties; including RRI facilities. The applicant further states that it is its policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved. On page 50, the applicant states,

“BMA of North Carolina has historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or other grouping/category or basis for being an underserved person. For example, Medicare (includes Medicare Advantage treatments) represented 81.38% of North Carolina dialysis treatments in BMA facilities in FY 2015. ...”

In Section L, page 53, the applicant reports that 87.9% of the patients who received treatments at Rocky Mount Kidney Center had some or all of their services paid for by Medicare or Medicaid in CY 2015. The table below shows the historical payment sources of the facility:

ROCKY MOUNT KIDNEY CENTER CY 2015	
Payor Source	Percent of Total Patients
Private Pay	1.49%
Commercial Insurance	6.90%
Medicare	79.10%
Medicaid	1.50%
Miscellaneous (Incl. VA)	3.70%
Other: Medicare/Commercial Insurance	7.30%
Total	100.00%

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant's market.

Percent of Population						
County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
Nash	16%	52%	48%	18%	11%	18%
Edgecombe	17%	54%	63%	26%	13%	17%
Halifax	18%	52%	61%	24%	17%	17%
Northampton	23%	52%	62%	26%	18%	16%
Statewide	15%	51%	36%	17%	10%	15%

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

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

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

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

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

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

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

C

In Section L.3, page 51, 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 52, the applicant states there have been no civil rights access complaints filed against any BMA North Carolina facilities within the last 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 50, the applicant projects that 88.1% of the in-center patients who will receive treatments at Rocky Mount Kidney Center in the second operating year (CY2018) will have some or all their services paid for by Medicare or Medicaid. The table below shows the projected Year 2 payment source for the facility for in-center patients:

ROCKY MOUNT KIDNEY CENTER	
Projected Payor Source PY2	In-Center Patients by Percent of Total
Private Pay	1.41%
Commercial Insurance	6.04%
Medicare	78.69%
Medicaid	1.43%
VA	4.48%
Medicare/Commercial Insurance	7.96%
Total	100.00%

In Section L.1, pages 49-50, the applicant states that projections are based on facility historical experience. The applicant's projected payment sources are consistent with the facility's historical (CY2015) payment sources as reported by the applicant in Section L.7, page 53 and in Section R, Form C. The applicant demonstrates that medically underserved groups will have adequate access to the services offered at Rocky Mount Kidney Center. 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 52, the applicant describes the range of means by which a person will have access to the dialysis services at Rocky Mount Kidney Center, 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

Exhibit M-1 contains a copy of correspondence to an area health professional training program expressing an interest on the part of the applicant to offer the facility as 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, Rocky Mount Kidney Center, proposes to add three dialysis stations for a total of 40 certified dialysis stations upon completion of this project, Project I.D.# L-10177-13 (relocate 12 stations to FMC South Rocky Mount) and Project I.D.# L-10182-13 (add seven for a total of 37 stations is complete and was certified on August 10, 2016).

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

The applicant, BMA operates the two existing dialysis centers in Nash County. BMA has one additional facility approved, but not yet operational. DaVita has been approved for Nash County Dialysis which will be the fourth dialysis center in Nash County. There are no other providers of dialysis services in Nash County.

NASH COUNTY DIALYSIS FACILITIES			
Dialysis Facility	Certified Stations 12/31/2015	% Utilization	Patients Per Station
Rocky Mount Kidney Center	42	100.00%	4.0000
FMC Spring Hope	15	85.00%	3.4000
FMC South Rocky Mount*	0*	00.00%	0.0000
Nash County Dialysis**	0**	00.00%	0.0000

Source: July 2016 SDR, Table A. *Con issued 11/19/13 for 12 stations. **CON issued 7/17/16 for 12 stations.

As shown in the table above, based on the most recent SDR, the two existing dialysis facilities in Nash County were operating above 80% (3.2 patients per station).

In Section N.1, page 55, 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 Nash County. BMA does not project to serve dialysis patients currently being served by another provider. The projected patient population for the BMA Rocky Mount facility begins with patient currently served by BMA, and a growth of that population consistent with the Nash County five year average annual change rate of 10.0% as published within the July 2016 SDR.

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 88% of the In-center treatments will be reimbursed by 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, I, K, L and O where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

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

- The applicant adequately demonstrates the need for the proposed project and that it is an effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.

- The applicant adequately demonstrates that Rocky Mount Kidney Center will continue to provide quality dialysis services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicant demonstrates that Rocky Mount Kidney Center will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (3) and (13) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

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

C

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 58-61, the applicant identifies three of its facilities, BMA Lumberton, BMA East Charlotte and RAI West College, that were cited in the past 18 months for deficiencies in compliance with 42 CFR Part 494, the Centers for Medicare and Medicaid (CMS) Conditions for Coverage of ESRD facilities. The applicant states the three facilities are back in full compliance with CMS Guidelines as of the date of submission of this application. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. The application is conforming to this criterion.

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

C

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

10 NCAC 14C .2203 PERFORMANCE STANDARDS

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

-NA- Rocky Mount Kidney Center is an existing facility.

.2203(b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.

-C- In Section C, pages 17-21, the applicant demonstrates that Rocky Mount Kidney Center will serve a total of 140 in-center patients at the end of Operating Year One for a utilization rate of 87.5% or 3.5 patients per station ($140 \text{ patients} / 40 \text{ stations} = 3.5000 / 4 = .8750$ or 87.5%). The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

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

-C- In Section C.1, pages 17-21, the applicant provides the assumptions and methodology used to project utilization of Rocky Mount Kidney Center. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.