

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 14, 2016

Findings Date: June 14, 2016

Project Analyst: Mike McKillip

Team Leader: Fatimah Wilson

Project ID #: J-11137-16

Facility: BMA of Fuquay-Varina Kidney Center

FID #: 980755

County: Wake

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

Project: Add five dialysis stations for a total of 28 stations upon completion of this project and Project I.D. # J-10339-14 (Add one dialysis station for a total of 23 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 BMA of Fuquay-Varina Kidney Center [BMA Fuquay-Varina] proposes to add five dialysis stations for a total of 28 certified dialysis stations upon completion of this project and Project I.D. # J-10339-14 (Add one dialysis station for a total of 23 stations).

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 January 2016 Semiannual Dialysis Report (SDR), the county need methodology shows there is no county need determination for Wake County. However, the

applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology, because the utilization rate reported for BMA Fuquay-Varina in the January 2016 SDR is 3.85 patients per station per week. This utilization rate was calculated based on 77 in-center dialysis patients and 20 certified dialysis stations as of June 30, 2015 (77 patients / 20 stations = 3.85 patients per station per week). [Note: As of December 4, 2015, the facility was certified for 22 stations and one station was pending certification pursuant to Project I.D. # J-10339-14.] Application of the facility need methodology indicates five additional stations are needed for this facility, as illustrated in the following table.

APRIL 1 REVIEW-JANUARY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/15		87.50%
Certified Stations		22
Pending Stations		1
Total Existing and Pending Stations		23
In-Center Patients as of 6/30/15 (SDR2)		77
In-Center Patients as of 12/31/14 (SDR1)		67
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	10
	Multiply the difference by 2 for the projected net in-center change	20
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/14	0.2985
(ii)	Divide the result of step (i) by 12	0.0249
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/15 until 12/31/15)	0.1493
(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	88.4925
(v)	Divide the result of step (iv) by 3.2 patients per station	27.6539
	and subtract the number of certified and pending stations to determine the number of stations needed	5

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is five stations. Step (C) of the facility need methodology states, “*The facility may apply to expand to meet the need established ..., up to a maximum of ten stations.*” The applicant proposes to add five new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2016 SMFP which is applicable to this review: Policy GEN-3: Basic Principles. Policy GEN-3 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.”

The applicant addresses Policy GEN-3 as follows:

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section B.4(a), pages 12-13, Section O, pages 64-67, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section B.4(b), page 14, Section L, pages 56-60, 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.4(c) and (d), pages 14-15, and Section N, pages 62-63. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

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

Conclusion

In summary, the applicant adequately demonstrates that the application is consistent with the facility need determination in the January 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.

The applicant, BMA Fuquay-Varina, proposes to add five dialysis stations for a total of 28 certified dialysis stations upon completion of this project and Project I.D. # J-10339-14 (Add one dialysis station for a total of 23 stations). BMA Fuquay-Varina currently offers a home dialysis program, including home hemodialysis and peritoneal dialysis.

Population to be Served

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

In Section C.8, page 24, the applicant provides the historical patient origin for BMA Fuquay-Varina for in-center, home hemodialysis, and peritoneal dialysis patients as of December 31, 2015, which is summarized in the following table:

BMA Fuquay-Varina Historical Patient Origin

County	In-Center	Home Hemodialysis	Peritoneal Dialysis
Wake	64	1	1
Harnett	13	0	0
Johnston	6	0	0
Other States	1	0	0
TOTAL	84	1	1

Source: Table on page 24 of the application.

In Section C.1, page 18, the applicant provides the projected patient origin for BMA Fuquay-Varina for in-center, home hemodialysis and peritoneal dialysis (PD) patients for the first two years of operation following completion of the project as follows:

	OPERATING YEAR 1 CY2018			OPERATING YEAR 2 CY2019			COUNTY PATIENTS AS A PERCENT OF TOTAL	
	IN-CENTER	HOME HEMO	PD	IN-CENTER	HOME HEMO	PD	YEAR 1	YEAR 2
Wake	70.9	4.3	7.8	73.5	5.5	8.2	79.1%	79.1%
Harnett	15.0	0	0	15.8	0	0	14.3%	14.3%
Johnston	6.9	0	0	7.3	0	0	6.6%	6.6%
Total	92.9	4.3	7.8	96.6	5.5	8.2	100%	100%

The applicant provides the assumptions and methodology used to project in-center patient origin on pages 18-19. The applicant adequately identifies the population to be served.

Analysis of Need

In Section B.2, pages 9-10, the applicant states the application is filed pursuant to the facility need methodology in the 2016 SMFP utilizing data from the January 2016 SDR, and it proposes to add five dialysis stations to BMA Fuquay-Varina for a total of 28 stations at that facility. The applicant used the following assumptions:

1. The applicant projects the first two full operating years of the project will be CY2018 and CY2019.
2. On December 31, 2015, BMA Fuquay-Varina was providing dialysis treatment for 84 in-center patients, including 64 patients who reside in Wake County, 13 patients who reside in Harnett County, six patients who reside in Johnston County, and one patient from out of state.
3. BMA Fuquay-Varina assumes the in-center patient population utilizing the facility who reside in Wake, Harnett, and Johnston counties will increase at the rate of 5 percent per year. On pages 18-19, the applicant states,

“BMA assumes that the patient population of BMA Fuquay Varina will continue to increase. BMA will apply a growth rate of 5% to the patient population residing in Wake, Harnett and Johnston Counties. The BMA Fuquay Varina facility census has been increasing at a rate greater than the Wake County Five Year Average Annual Change Rate. ... The Facility Need Methodology measures the change in facility census for the six months ended June 30, 2015 and, in a practical sense, doubles that six month growth to calculate a possible growth for the year (2015, in this case). In this case the methodology would have projected a census of 87 patients for the year ended December 31, 2015. This would have been a growth rate of 29.85% for 2015.

BMA Fuquay Varina dialysis facility had a census of 84 patients as of December 31, 2015. Thus the growth rate of the facility for 2015 was 25.27%, slightly less than the growth rate calculated by the methodology.

BMA does not believe the facility census will continue growth at this level. However, BMA also does not believe that it is appropriate to apply the Wake County Five Year Average Annual Change Rate of 5.0% to just the Wake County patient population of the facility. BMA assumes the in-center patient population will increase at 5%.”

Projected Utilization

The applicant’s methodology is illustrated in the following table.

	In-Center
The applicant begins with the facility census of Wake, Harnett and Johnston County in-center residents as of December 31, 2015.	83
The census of in-center patients is increased by 5% to project the census forward one year to December 31, 2016.	$(83 \times 0.05) + 83 = 87.2$
The applicant subtracts one patient from the projected in-center census who is project to convert to home hemodialysis.	$87.2 - 1 = 86.2$
The census of in-center patients is increased by 5% to project the census forward one year to December 31, 2017.	$(86.2 \times 0.05) + 86.2 = 90.5$
The applicant subtracts one patient from the projected in-center census who is project to convert to home hemodialysis.	$90.5 - 1 = 89.5$
The census of in-center patients is increased by 5% to project the census forward one year to December 31, 2018.	$(89.5 \times 0.05) + 89.5 = 93.9$
The applicant subtracts one patient from the projected in-center census who is project to convert to home hemodialysis. This is the projected ending census for Operating Year 1.	$93.9 - 1 = 92.9$
The census of in-center patients is increased by 5% to project the census forward one year to December 31, 2019.	$(92.9 \times 0.05) + 92.9 = 97.6$
The applicant subtracts one patient from the projected in-center census who is project to convert to home hemodialysis. This is the projected ending census for Operating Year 2.	$97.6 - 1 = 96.6$

The applicant projects to serve 93 in-center patients or 3.3 patients per station per week ($93/28 = 3.3$) by the end of Operating Year 1 and 97 in-center patients or 3.5 patients per station per week ($97/28 = 3.5$) by the end of Operating Year 2 for the proposed 28-station 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 January 2016 SDR indicates that BMA Fuquay-Varina operated at a utilization rate of 96 percent (3.85 patients per station per week) as of June 30, 2015. Based on data reported in the SDR, during the period from June 30, 2014 to June 30, 2015, the in-center census at BMA Fuquay-Varina increased from 66 to 77 patients, which is an annual rate of growth of 17 percent. In this

application, the applicant assumes a projected annual rate of growth of 5 percent for the in-center patient census at BMA Fuquay-Varina, which is equal to the Wake County Five Year Average Annual Change Rate (2010-2014), but lower than the applicant's recent historical experience. Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

With regard to BMA Fuquay-Varina's home dialysis program, on page 20, the applicant states:

"The home program of BMA Fuquay Varina had one PD patient and one HH patient as of December 31, 2015. These patients were identified as 'new starts', or patients just beginning to train for home dialysis. The Licensure and Certification Section of DHHS desires to certify a home program with patients in training. Thus, once the program was thought to be ready, in anticipation of survey, BMA sought permission from Licensure and Certification Section to commence training two patients (one in each modality). ... In CON Project ID # J-10339-14 BMA assumed that home patients residing on the south side of Wake County would transfer their care to the facility once the home program was certified. BMA continues to expect those patients will transfer their care as a function of patient convenience...."

BMA assumed that each year after certification of the home program, one patient from the in-center program would convert to Home Hemodialysis. As has been noted in this application, the facility home program was certified in February 2016. BMA will assume one patient per year to change to the home hemodialysis modality."

Access

In Section L.1(a), pages 56-57, the applicant states that each of BMA's 104 facilities in 42 North Carolina Counties has a patient population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, and other underserved persons. In Section L.6, page 60, the applicant reports that 87 percent of BMA Fuquay-Varina's patients were Medicare or Medicaid recipients in CY2015. In Section L.1, page 57, the applicant projects 87% of its patients will be Medicare or Medicaid recipients. The applicant adequately demonstrates the extent to which all residents of the service area, including underserved groups, are likely to have access to its services.

Conclusion

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

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons,

racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

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

CA

In Section E.1, page 28, 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 BMA Fuquay-Varina facility.
- Apply for Fewer Stations – The applicant states it considered applying for fewer than five stations but rejected the alternative because it would fail to meet the need based on the projected levels of utilization for BMA Fuquay-Varina.
- Transfer stations from FMC Apex to BMA Fuquay-Varina – The applicant states it considered transferring stations from FMC Apex to the BMA Fuquay-Varina facility, but rejected the alternative because the applicant anticipates changes to physician admitting practices “*in the very near future*” that will increase utilization of the FMC Apex facility.

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 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 BMA of Fuquay-Varina 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 BMA of Fuquay-Varina Kidney Center shall develop and operate no more than five additional dialysis stations for a total of no more than 28 certified stations upon completion of the project and Project I.D. # J-10339-14, which shall include any isolation or home hemodialysis stations.**

3. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA of Fuquay-Varina Kidney Center shall install plumbing and electrical wiring through the walls for five additional dialysis stations for a total of 28 dialysis stations which shall include any home hemodialysis training or isolation stations.**
 4. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA of Fuquay-Varina Kidney Center 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, BMA Fuquay-Varina, proposes to add five dialysis stations for a total of 28 certified dialysis stations upon completion of the project.

Capital and Working Capital Costs

In Section F.1, page 30, the applicant states that it projects \$272,000 in capital costs to develop this project. In Sections F.10-F.12, page 33, the applicant states there will be no start-up expenses or initial operating expenses incurred for this project.

	Total Capital Costs
Construction Contract	\$250,000
Equipment/furniture	\$22,000
Total Capital Costs	\$272,000

Availability of Funds

In Section F.2, page 31, the applicant states it will finance the capital costs with accumulated reserves. Exhibit F-1 contains a letter dated March 15, 2016 from the Assistant Treasurer for Fresenius Medical Care Holdings, Inc. (FMCH), the parent company for the applicant, which states the applicant has adequate funds for the proposed project. Exhibit F-2 contains the Consolidated Financial Statements for FMCH which indicates that it had \$195 million in cash and cash equivalents as of December 31, 2014. The applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project.

Financial Feasibility

The applicant provided pro forma financial statements for the first two years of the project. In the pro forma financial statement (Form B), the applicant projects that revenues will exceed

operating expenses in the first two operating years of the project, as shown in the table below.

	CY2018	CY2019
Total Net Revenue	\$6,104,711	\$6,495,674
Total Operating Expenses	\$4,603,078	\$4,856,372
Net Income	\$1,501,633	\$1,639,303

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See the financial section of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization 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 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, BMA Fuquay-Varina, proposes to add five dialysis stations for a total of 28 certified dialysis stations upon completion of the project.

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

The applicant operates eleven dialysis centers in Wake County. Also, BMA has been approved to develop another facility in Wake County, FMC Northern Wake, but the facility is not yet operational. Wake Forest Dialysis Center (DaVita) is the only other provider of dialysis services in Wake County, and operates just one dialysis center, as shown in the table below.

Wake County Dialysis Facilities

Dialysis Facility	Certified Stations 6/30/15	CON Issued Not Certified	% Utilization	Patients Per Station
BMA of Fuquay-Varina	20	1	96.25%	3.9
BMA of Raleigh Dialysis	50	0	81.50%	3.3
BMA Cary	28	0	71.43%	2.9
FMC Apex (BMA)	20	0	61.25%	2.5
FMC Central Raleigh (BMA)	19	0	72.37%	2.9
FMC Eastern Wake (BMA)	14	0	108.93%	4.4
FMC Millbrook (BMA)	17	0	83.82%	3.4
FMC New Hope (BMA)	36	0	76.39%	3.1
FMC Northern Wake (BMA)	0	13	NA	NA
Southwest Wake (BMA)	31	-1	92.74%	3.7
BMA Wake Dialysis	50	0	99.00%	4.0
Wake Forest Dialysis (DaVita)	20	0	91.25%	3.7
Zebulon Kidney Center (BMA)	30	-2	82.50%	3.3

Source: January 2016 SDR, Table A.

As shown in the table above, eight of the twelve operational Wake County dialysis facilities are operating above 80% utilization (3.2 patients per station), and nine of the twelve facilities are operating at or above 75% utilization (3.0 patients per station).

BMA Fuquay-Varina proposes to add five in-center dialysis stations for a total of 28 dialysis stations upon project completion. BMA Fuquay-Varina was serving 77 patients weekly on 20 stations, which is 3.9 patients per station or 96.25% of capacity, as of June 30, 2015. 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 applicant does not propose to establish a new facility. The applicant provides reasonable projections for the in-center patient population it proposes to serve on pages 18-21 of the application. The growth projections are based on a projected 5.0% average annual growth rate in the number of in-center dialysis patients at the BMA Fuquay-Varina facility. At the end of Operating Year Two, BMA Fuquay-Varina projects utilization will be 3.5 in-center patients per station per week (97 patients / 28 dialysis stations = 3.5), which is 88% of capacity. The applicant adequately demonstrates the need to develop five additional dialysis stations at the existing facility based on the number of in-center patients it proposes to serve.

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.

In Section H.1, page 42, the applicant provides the current staffing for the facility, which includes 15.45 full-time equivalent (FTE) employees, and the proposed staffing for the facility following completion of the project, which includes 19.2 FTE employees. In Section H.3, page 43, 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-6 contains a copy of a letter from James Godwin, M.D., expressing his interest in serving as the Medical Director for the facility. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

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

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In Section I.1, page 45, the applicant includes a list of providers of the necessary ancillary and support services. Exhibit I-6 contains a letter from the medical director of the facility expressing his support for the proposed project. The applicant 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;

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In Section L.7, page 60, the applicant reports that 87% of the in-center patients who received treatments at BMA Fuquay-Varina had some or all of their services paid for by Medicare or Medicaid in CY2015. The table below shows the historical (CY2015) payment source for the facility for in-center patients:

Payment Source	In-Center
Private Pay	3.25%
Commercial Insurance	6.24%
Medicare	67.49%
Medicaid	2.20%
VA	3.92%
Medicare/Commercial Insurance	16.91%
Total	100.00%

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

Percent of Population						
County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
Wake	10%	51.3%	39%	12%	5%	14%
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 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 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

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In Section L.1(b), page 57, the applicant projects that 87% of the in-center patients who will receive treatments at BMA Fuquay-Varina in the second operating year (CY2019) will have some or all of their services paid for by Medicare or Medicaid. The table below shows the projected Year 2 payment source for the facility for in-center and home dialysis patients:

Payment Source	Percent of Total	In-Center	Home Hemo	PD
Private Pay	2.9%	3.25%	0.0%	0.0%
Commercial Insurance	8.7%	6.24%	33.3%	33.3%
Medicare	67.0%	67.49%	56.7%	56.7%
Medicaid	1.9%	2.20%	0.0%	0.0%
VA	2.9%	3.92%	10.0%	10.0%
Medicare/Commercial Insurance	16.5%	16.91%	0.0%	0.0%
Total	100%	100%	100%	100%

In Section L.1, pages 56-57, the applicant provides the assumptions used to project payer mix. 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 60. The applicant demonstrated that medically underserved groups will have adequate access to the services offered at BMA Fuquay-Varina. 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.

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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 Fuquay-Varina, 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.

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In Section M.1, page 61, the applicant states that BMA Fuquay-Varina has established relationships with local community training programs, and the applicant will continue to offer the same opportunities to local health professional training programs. 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.

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The applicant, BMA Fuquay-Varina, proposes to add five dialysis stations for a total of 28 certified dialysis stations upon completion of the project.

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

The applicant operates eleven dialysis centers in Wake County. Also, BMA has been approved to develop another facility in Wake County, FMC Northern Wake, but the facility is not yet operational. Wake Forest Dialysis Center (DaVita) is the only other provider of dialysis services in Wake County, and operates just one dialysis center, as shown in the table below.

Wake County Dialysis Facilities

Dialysis Facility	Certified Stations 6/30/15	CON Issued Not Certified	% Utilization	Patients Per Station
BMA of Fuquay-Varina	20	1	96.25%	3.9
BMA of Raleigh Dialysis	50	0	81.50%	3.3
BMA Cary	28	0	71.43%	2.9
FMC Apex (BMA)	20	0	61.25%	2.5
FMC Central Raleigh (BMA)	19	0	72.37%	2.9
FMC Eastern Wake (BMA)	14	0	108.93%	4.4
FMC Millbrook (BMA)	17	0	83.82%	3.4
FMC New Hope (BMA)	36	0	76.39%	3.1
FMC Northern Wake (BMA)	0	13	NA	NA
Southwest Wake (BMA)	31	-1	92.74%	3.7
BMA Wake Dialysis	50	0	99.00%	4.0
Wake Forest Dialysis (DaVita)	20	0	91.25%	3.7
Zebulon Kidney Center (BMA)	30	-2	82.50%	3.3

Source: January 2016 SDR, Table A.

As shown in the table above, eight of the twelve operational Wake County dialysis facilities are operating above 80% utilization (3.2 patients per station per week), and nine of the twelve facilities are operating at or above 75% utilization (3.0 patients per station per week).

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 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 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 where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

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

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

Therefore, the application is conforming to this criterion.

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

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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 68-70, the applicant identifies two of its facilities, BMA Lumberton and BMA East Charlotte, 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 both 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.

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The application is conforming with all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. The specific criteria are discussed below:

10 NCAC 14C .2203 PERFORMANCE STANDARDS

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

-NA- BMA Fuquay-Varina is an existing facility.

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

-C- In Section C.1, page 18, the applicant projects to serve 93 in-center patients by the end of Operating Year 1, which is 3.3 patients per station per week ($93 / 28 = 3.3$). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

-C- In Section C.1, pages 18-21, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.