

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: November 20, 2015

Findings Date: November 20, 2015

Project Analyst: Mike McKillip

Team Leader: Fatimah Wilson

Project ID #: J-11097-15

Facility: BMA Wake Dialysis Clinic

FID #: 956094

County: Wake

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

Project: Add three dialysis stations for a total of 50 stations upon completion of this project, Project I.D. #J-10152-13 (relocate 10 stations to FMC Northern Wake), Project I.D. #J-10183-13 (add 10 stations to BMA Wake Dialysis), and Project I.D. #J-11068-15 (relocate 3 stations to FMC Northern Wake)

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 Wake Dialysis Clinic [BMA Wake Dialysis] proposes to add three dialysis stations for a total of 50 certified dialysis stations upon completion of this project and Project I.D. #J-10152-13 (relocate 10 stations to FMC Northern Wake), Project I.D. #J-10183-13 (add 10 stations to BMA Wake Dialysis), and Project I.D. #J-11068-15 (relocate 3 stations to FMC Northern Wake).

Need Determination

The 2015 State Medical Facilities Plan (2015 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2015 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of one dialysis station in Wake County; therefore, based on the county need methodology, there is no need for additional stations in 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 Wake Dialysis in the July 2015 SDR is 3.86 patients per station. This utilization rate was calculated based on 193 in-center dialysis patients and 50 certified dialysis stations as of December 31, 2014 (193 patients / 50 stations = 3.86 patients per station). Application of the facility need methodology indicates eleven additional stations are needed for this facility, as illustrated in the following table.

OCTOBER 1 REVIEW - JULY 2015 SDR

Required SDR Utilization		80%
Center Utilization Rate as of 12/31/14		96.5%
Certified Stations		50
Pending Stations		10
Total Existing and Pending Stations		60
In-Center Patients as of 12/31/14 (July 2015 SDR) (SDR2)		193
In-Center Patients as of 6/30/14 (January 2015 SDR) (SDR1)		177
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	16
	Multiply the difference by 2 for the projected net in-center change	32
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/14	0.1808
(ii)	Divide the result of step (i) by 12	0.0151
(iii)	Multiply the result of step (ii) by 12 (the number of months from 12/31/13 until 12/31/14)	0.1808
(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	227.8972
(v)	Divide the result of step (iv) by 3.2 patients per station	71.2165
	and subtract the number of certified and pending stations as recorded in SDR2 to determine the number of stations needed	11

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is eleven 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 and, therefore, is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2015 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 64-69, 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), pages 13-15, 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 15-16, 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 July 2015 SDR and Policy GEN-3. Therefore, the application is conforming to this criterion.

- (2) Repealed effective July 1, 1987.

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

C

The applicant, BMA Wake Dialysis, proposes to add three dialysis stations for a total of 50 stations upon completion of this project, Project I.D. #J-10152-13 (relocate 10 stations to FMC Northern Wake), Project I.D. #J-10183-13 (add 10 stations to BMA Wake Dialysis), and Project I.D. #J-11068-15 (relocate 3 stations to FMC Northern Wake).

Population to be Served

On page 361, the 2015 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 Wake Dialysis for in-center and home patients as of June 30, 2015, which is summarized in the following table:

	IN-CENTER		HOME*	
	PATIENTS	PERCENT	PATIENTS	PERCENT
Wake	194	98.0%	36	85.7%
Franklin	2	1.0%	1	2.3%
Harnett	0	0.0%	1	2.3%
Johnston	2	1.0%	3	7.1%
Lee	0	0.0%	1	2.3%
Total	198	100.0%	42	100.0%

*The “Home” category includes home hemodialysis and peritoneal dialysis patients.

In Section C.1, page 19, the applicant provides the projected patient origin for BMA Wake Dialysis for in-center and home patients for the first two years of operation following completion of the project as follows:

	OPERATING YEAR 1 CY2017		OPERATING YEAR 2 CY2018		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	IN-CENTER	HOME*	IN-CENTER	HOME*	YEAR 1	YEAR 2
Wake	187.5	31.9	196.8	33.4	95.4%	95.6%
Franklin	2	1	2	1	1.4%	1.3%
Harnett	0	1	0	1	0.5%	0.4%
Johnston	2	3	2	3	2.3%	2.2%
Lee	0	1	0	1	0.5%	0.4%
Total	191.5	37.9	200.8	39.4	100%	100%

*The "Home" category includes home hemodialysis and peritoneal dialysis patients.

The applicant provides the assumptions and methodology used to project patient origin on page 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 2015 SMFP utilizing data from the July 2015 SDR, and it proposes to add three dialysis stations to BMA Wake Dialysis for a total of 50 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 CY2017 and CY2018.
2. On June 30, 2015, BMA Wake Dialysis was providing dialysis treatment for 198 in-center patients, including 194 patients who reside in Wake County, two patients who reside in Franklin County, and two patients who reside in Johnston County.
3. BMA Wake Dialysis assumes the Wake County ESRD in-center patient population utilizing the facility will increase at the rate of 5.0 percent per year. On page 19, the applicant states,

"BMA assumes that the BMA Wake patient population comprised of Wake County residents is a part of the Wake County dialysis patient population as a whole, and that population will continue to increase at a rate commensurate with the Wake County Five Year Average Annual Change Rate as published in the July 2015 SDR. That rate is 5.0%. ... BMA assumes that patients from other counties, dialyzing with BMA Wake, are at the facility by patient choice. BMA assumes these patients will continue to dialyze at the facility. However, BMA does not project any increase in this patient population. These patients are added into the projections of future patient populations at appropriate points in time."

Also, on pages 19-20, the applicant states the proposed project will follow the completion of three previously approved projects, which the applicant describes as follows:

- a. *CON Project ID # J-10152-13, (relocation of 10 stations to FMC Northern Wake: in this project BMA proposed that 21 in-center patients, five PD patients, and three HH patients would transfer their care to the new FMC Northern Wake upon certification of the facility. BMA will continue these projections within this application.*
- b. *CON Project ID # J-10183-13, addition of 10 stations at BMA Wake.*
- c. *CON Project ID # J-11068-15, relocation of 3 stations to FMC Northern Wake: in this project, BMA proposed that eight in-center patients would transfer their care to the new FMC Northern Wake upon completion of the project. BMA will continue these projections within this application.”*

Projected Utilization

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

	In-Center
BMA begins with the facility census of Wake County in-center residents as of June 30, 2015.	194
The census of Wake County in-center patients is increased by one half of 5.0% (0.025%) to project the census forward for six months to December 31, 2015.	$(194 \times 0.025) + 194 = 198.9$
Subtract 21 in-center patients projected to transfer to FMC North Wake upon completion of Project I.D. # J-10152-13.	$198.9 - 21 = 177.9$
Add four in-center patients from Franklin and Johnston counties.	$177.9 + 4 = 181.9$
Project census of Wake County in-center patients forward by three months to March 31, 2016.	$(177.9 \times 0.0125) + 177.9 = 180.1$
Subtract 8 in-center patients projected to transfer to FMC North Wake upon completion of Project I.D. # J-11068-15.	$180.1 - 8 = 172.1$
Project census of Wake County in-center patients forward by nine months to December 31, 2016.	$(172.1 \times 0.0375) + 172.1 = 178.5$
The census of Wake County in-center patients is increased by 5.0% for one year to December 31, 2017.	$(178.5 \times 0.05) + 178.5 = 187.5$
Add four in-center patients from Franklin and Johnston counties. This is the projected ending census for Operating Year 1.	$187.5 + 4 = 191.5$
The census of Wake County in-center patients is again increased by 5.0% for one year to December 31, 2018.	$(187.5 \times 0.05) + 187.5 = 196.8$
Add four in-center patients from Franklin and Johnston counties. This is the projected ending census for Operating Year 2.	$196.8 + 4 = 200.8$

The applicant projects to serve 191 in-center patients or 3.8 patients per station ($191/50 = 3.8$) by the end of Operating Year 1 and 200 in-center patients or 4.0 patients per station ($200/50 = 4.0$) by the end of Operating Year 2 for the proposed 50-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 July 2015 SDR indicates that BMA Wake Dialysis operated at a utilization rate of 96.5 percent (3.9 patients per station). In this application, the applicant assumes a projected annual rate of growth of 5.0% for the Wake County in-center patient census at BMA Wake Dialysis, which is consistent with the Wake

County Five Year Average Annual Change Rate (2010-2014). Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

Access

In Section L.1(a), pages 56-57, the applicant states that each of BMA's 102 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. The applicant projects 79% 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 three additional stations at BMA Wake Dialysis, 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 Wake Dialysis facility.
- Apply for More Stations – The applicant states it considered applying for more than three stations but rejected the alternative because the BMA Wake Dialysis's physical plant could not accommodate more than a total of 50 stations.

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 Wake Dialysis 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 Wake Dialysis shall develop and operate no more than three additional dialysis stations for a total of no more than 50 certified stations upon completion of this project, Project I.D. #J-10152-13, Project I.D. #J-10183-13, and Project I.D. #J-11068-15, which shall include any isolation or home hemodialysis stations.**
 3. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Wake Dialysis 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

In Section F.1, page 29, the applicant states that it will not incur any capital costs to develop this project. In Section F.10-F.12, the applicant states there will be no start-up expenses or initial operating expenses incurred for this 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.

	CY2017	CY2018
Total Net Revenue	\$10,018,008	\$10,941,740
Total Operating Expenses	\$8,672,191	\$9,213,990
Net Income	\$1,345,817	\$1,727,750

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. See Criterion (3) for discussion of utilization projections which are 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 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 Wake Dialysis, proposes to add three dialysis stations for a total of 50 stations upon completion of this project, Project I.D. #J-10152-13 (relocate 10 stations to FMC Northern Wake), Project I.D. #J-10183-13 (add 10 stations to BMA Wake Dialysis), and Project I.D. #J-11068-15 (relocate 3 stations to FMC Northern Wake).

On page 361, the 2015 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. 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 12/31/14	% Utilization	Patients Per Station
BMA of Fuquay-Varina	19	88.16%	3.5
BMA of Raleigh Dialysis	50	81.00%	3.2
BMA Cary	28	67.86%	2.7
FMC Apex (BMA)	17	72.06%	2.9
FMC Central Raleigh (BMA)	15	95.00%	3.8
FMC Eastern Wake (BMA)	14	100.00%	4.0
FMC Millbrook (BMA)	17	88.24%	3.5
FMC New Hope (BMA)	36	76.39%	3.1
Southwest Wake (BMA)	31	85.48%	3.4
BMA Wake Dialysis	50	96.50%	3.9
Wake Forest Dialysis (DaVita)	20	91.25%	3.7
Zebulon Kidney Center (BMA)	30	82.50%	3.3

Source: July 2015 SDR, Table A.

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

BMA Wake Dialysis proposes to add three in-center dialysis stations for a total of 50 dialysis stations upon project completion. BMA Wake Dialysis was serving 193 patients weekly on 50 stations, which is 3.86 patients per station or 96.5% of capacity, as of December 31, 2014. Dialysis facilities that operate four shifts per week (2 per day on alternate days) have a capacity of four patients per station. 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 19-24 of the application. The growth projections are based on a projected 5.0% average annual growth rate in the number of Wake County dialysis patients at the BMA Wake Dialysis facility. At the end of Operating Year Two, BMA Wake Dialysis projects the utilization will be 3.8 in-center patients per station (191 patients / 50 dialysis stations = 3.8), which is 96% of capacity. The applicant adequately demonstrates the need to develop three 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 and proposed staffing for the facility, which includes 45.52 full-time equivalent (FTE) employees. The applicant does not propose any changes in staffing as a result of this project. In Section H.3, page 43, the applicant describes its experience and process for recruiting and retaining staff. Exhibit I-6 contains a copy of a letter from Michael Monahan, 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.

C

In Section I.1, page 46, 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, and Exhibit C-1 contains a letter of support for the project signed by existing patients of the facility. 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 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 R, page 86, the applicant reports that 79% of the in-center patients who received treatments at BMA Wake Dialysis had some or all of their services paid for by Medicare or Medicaid in the past year. The table below shows the historical (CY2014) payment source for the facility for in-center patients:

Payment Source	In-Center
Self Pay/Indigent/Charity	3.02%
Commercial Insurance	16.75%
Medicare	64.48%
Medicaid	2.19%
VA	1.05%
Medicare/Commercial Insurance	12.52%
Total	100.00%

The Division of Medical Assistance (DMA) maintains a website which provides the number of persons eligible for Medicaid in North Carolina, and estimates the percentage of uninsured people for each county. The following table illustrates those percentages for Wake County and statewide.

	2010 Total # of Medicaid Eligibles as % of Total Population *	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *
Wake	10%	3.3%	18.4%
Statewide	17%	6.7%	19.7%

*More current data, particularly with regard to the estimated uninsured percentages, was not available.

Although the majority of Medicaid eligibles are children under the age of 21, they represent a very small percentage of those who utilize the services offered by dialysis facilities. In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older. (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59*).¹

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina, as well as data sorted by age, race or gender. But it does not include information on the number of elderly, handicapped, minorities or women utilizing health services.

However, the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report* provides prevalence data on North Carolina dialysis patients by age, race and gender on page 59, summarized as follows:

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

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: Southeastern Kidney Council Network 6 Inc. 2014 Annual Report.²

The applicant demonstrates that it 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

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. On page 59, 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.

²<http://www.esrdnetwork6.org/utills/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

- (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 R, page 87, the applicant projects that 79% of the in-center patients who will receive treatments at BMA Wake Dialysis in the second operating year (CY2018) 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 patients:

Payment Source	In-Center
Self Pay/Indigent/Charity	3.42%
Commercial Insurance	10.88%
Medicare	67.61%
Medicaid	2.71%
VA	1.39%
Medicare/Commercial Insurance	14.00%
Total	100.00%

In Section L, pages 57-58, the applicant provides the assumptions used to project payer mix. The applicant's projected payment sources are consistent with the facility's historical (CY2014) payment sources as reported by the applicant in Section R, page 86. The applicant demonstrated that medically underserved population will have adequate access to the services offered at BMA Wake Dialysis. 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 Wake Dialysis, 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 BMA Wake Dialysis 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.

C

The applicant, BMA Wake Dialysis, proposes to add three dialysis stations for a total of 50 stations upon completion of this project, Project I.D. #J-10152-13 (relocate 10 stations to FMC Northern Wake), Project I.D. #J-10183-13 (add 10 stations to BMA Wake Dialysis), and Project I.D. #J-11068-15 (relocate 3 stations to FMC Northern Wake).

On page 361, the 2015 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. 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 12/31/14	% Utilization	Patients Per Station
BMA of Fuquay-Varina	19	88.16%	3.5
BMA of Raleigh Dialysis	50	81.00%	3.2
BMA Cary	28	67.86%	2.7
FMC Apex (BMA)	17	72.06%	2.9
FMC Central Raleigh (BMA)	15	95.00%	3.8
FMC Eastern Wake (BMA)	14	100.00%	4.0
FMC Millbrook (BMA)	17	88.24%	3.5
FMC New Hope (BMA)	36	76.39%	3.1
Southwest Wake (BMA)	31	85.48%	3.4
BMA Wake Dialysis	50	96.50%	3.9
Wake Forest Dialysis (DaVita)	20	91.25%	3.7
Zebulon Kidney Center (BMA)	30	82.50%	3.3

Source: July 2015 SDR, Table A.

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

In Section N.1, pages 62-63, the applicant discusses how the proposed project would 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 81% 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 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) 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 68-69, 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.

C

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:

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

(a) An applicant that proposes to increase stations in an existing certified facility or relocate stations must provide the following information:

.2202(a)(1) Utilization rates;

-C- In Section P, page 71, the applicant reports the facility had 193 in-center patients and a 96.5% utilization rate as of December 31, 2014.

.2202(a)(2) Mortality rates;

-C- In Section P, page 71, the applicant reports 2012, 2013 and 2014 facility mortality rates of 13.4%, 11.9% and 7.3%, respectively.

.2202(a)(3) The number of patients that are home trained and the number of patients on Home dialysis;

-NA- In Section P, page 71, the applicant reports that BMA Wake Dialysis had 8 home hemodialysis patients and 34 peritoneal dialysis patients as of June 30, 2015.

.2202(a)(4) The number of transplants performed or referred;

-C- In Section P, page 72, the applicant states BMA Wake Dialysis referred 34 patients for transplant evaluation in 2015.

.2202(a)(5) The number of patients currently on the transplant waiting list;

-C- In Section P, page 72, the applicant states that BMA Wake Dialysis has 27 patients on the transplant waiting list.

.2202(a)(6) Hospital admission rates, by admission diagnosis, i.e., dialysis related versus Non-dialysis related;

-C- In Section P, page 72, the applicant reports a total of 183 hospital admissions, of which 137 were non-dialysis related and 46 were dialysis-related.

.2202(a)(7) The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during the last calendar year.

-C- In Section P, page 72, the applicant reports that in 2015 there are currently four patients with an infectious disease, and no patients converted to infectious status in the last calendar year.

(b) An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations

shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:

.2202(b)(1) For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100

-NA- BMA Wake Dialysis is an existing facility.

.2202(b)(2) For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:

- (A) timeframe for initial assessment and evaluation of patients for transplantation,*
- (B) composition of the assessment/evaluation team at the transplant center,*
- (C) method for periodic re-evaluation,*
- (D) criteria by which a patient will be evaluated and periodically Re-evaluated for transplantation, and,*
- (E) Signatures of the duly authorized persons representing the facilities and the agency providing the services.*

-NA- BMA Wake Dialysis is an existing facility.

.2202(b)(3) For new or replacement facilities, documentation that power and water will be available at the proposed site.

-NA- BMA Wake Dialysis is an existing facility.

.2202(b)(4) Copies of written policies and procedures for back up for electrical service in the event of a power outage.

-C- Exhibit K-3 contains a copy of written policies and procedures for back up for electrical service in the event of a power outage.

.2202(b)(5) For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.

-NA- BMA Wake Dialysis is an existing facility.

.2202(b)(6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*

-C- In Section P, page 73, the applicant states that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.

.2202(b)(7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*

-C- In Section C.1, page 19, BMA Wake Dialysis provides projected patient origin, based on historical experience, for the first two years of operation following completion of the project. The discussion regarding patient origin assumptions found in Criterion (3) is incorporated herein by reference.

.2202(b)(8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*

-NA- BMA Wake Dialysis is an existing facility.

.2202(b)(9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement for such services.*

-C- In Section P, page 74, the applicant states, “BMA will admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.”

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 Wake Dialysis 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 19, the applicant projects to serve 191 in-center patients by the end of Operating Year 1, which is 3.8 patients per station ($191 / 50 = 3.8$). The discussion regarding utilization assumptions 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 19-22 the applicant provides the assumptions and methodology used to project utilization of the proposed facility. The discussion regarding utilization assumptions found in Criterion (3) is incorporated herein by reference.

10 NCAC 14C .2204 SCOPE OF SERVICES

To be approved, the applicant must demonstrate that the following services will be available:

.2204(1) *Diagnostic and evaluation services;*

-C- These services are provided by WakeMed. See Section P, page 74.

.2204(2) *Maintenance dialysis;*

-C- Provided at BMA Wake Dialysis. See Section P, page 75.

.2204(3) *Accessible self-care training;*

-C- Provided by BMA Wake Dialysis. See Section P, page 75.

.2204(4) *Accessible follow-up program for support of patients dialyzing at home;*

-C- Provided by BMA Wake Dialysis. See Section P, page 75.

.2204(5) *X-ray services;*

-C- These services are provided by WakeMed. See Section P, page 75.

.2204(6) *Laboratory services;*

-C- Provided by Spectra Labs. See Section P, page 75.

.2204(7) *Blood bank services;*

- C- Provided by WakeMed. See Section P, page 75.
- .2204(8) *Emergency care;*
- C- Provided by staff on-site and by local hospitals via phone call to 911. See Section P, page 75.
- .2204(9) *Acute dialysis in an acute care setting;*
- C- Provided by WakeMed. See Section P, page 75.
- .2204(10) *Vascular surgery for dialysis treatment patients*
- C- Provided by referral to Carolina Vascular, Wake Surgical, North Raleigh Surgical, or Carolina Surgery. See Section P, page 75.
- .2204(11) *Transplantation services;*
- C- Provided by Duke University Medical Center. See Section P, page 76.
- .2204(12) *Vocational rehabilitation counseling and services; and,*
- C- Provided by referral to Division of Vocational Rehabilitation. See Section P, page 76.
- .2204(13) *Transportation*
- C- Provided by Tri-Star, Johnston Ambulance Services, and Wake Coordinated Transportation. See Section P, page 76.

10 NCAC 14C .2205 STAFFING AND STAFF TRAINING

- .2205(a) *To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R. Section 405.2100.*
- C- In Section H.1, page 42, the applicant provides the proposed staffing. In Section H.2, page 42, the applicant states the proposed facility will comply with all staffing requirements set forth in 42 C.F.R. Section 494 (formerly 405.2100). The applicant adequately demonstrates that sufficient staff is proposed for the level of dialysis services to be provided. The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

.2205(b) To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.

-C- See Section P, page 76, and Exhibits H-1 and H-2.