

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 17, 2019

Findings Date: December 17, 2019

Project Analyst: Celia C. Inman

Team Leader: Lisa Pittman

Project ID #: J-11770-19

Facility: BMA of Fuquay Varina Kidney Center

FID #: 980755

County: Wake

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

Project: Add no more than 1 dialysis station for a total of no more than 29 stations upon project completion

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications of North Carolina, Inc. (hereinafter referred to as “the applicant” or BMA) proposes to add one dialysis station to the existing BMA of Fuquay Varina Kidney Center (BMA Fuquay) for a total of 29 dialysis stations upon project completion.

Need Determination

The 2019 State Medical Facilities Plan (2019 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table D, page 64, in the July 2019 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of 15 stations in Wake County; therefore, there is no county need determination for new dialysis stations for Wake County.

However, the applicant is eligible to apply for additional dialysis stations in an existing facility based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. The utilization rate reported for BMA Fuquay in the July 2019 SDR, page 51, is 3.39 patients per station per week, or 84.82%, based on 95 in-center dialysis patients and 28 certified dialysis stations [$95 / 28 = 3.3928$; $3.3928 / 4 = 0.8482$]. Therefore, BMA Fuquay is eligible to apply for additional stations based on the facility need methodology.

Application of the facility need methodology indicates up to four additional stations may be needed at this facility, as illustrated in the following the table:

BMA Fuquay		
OCTOBER 1 REVIEW-JULY 2019 SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/18		84.82%
Certified Stations		28
Pending Stations		0
Total Existing and Pending Stations		28
In-Center Patients as of 12/31/18 (July 2019 SDR) (SDR2)		95
In-Center Patients as of 6/30/18 (January 2019 SDR) (SDR1)		92
Step	Description	Result
	Difference (SDR2 - SDR1)	3
(i)	Multiply the difference by 2 for the projected net in-center change	6
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/18	0.0652
(ii)	Divide the result of Step (i) by 12	0.0054
(iii)	Multiply the result of Step (ii) by 12	0.0652
(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	101.1957
(v)	Divide the result of Step (iv) by 3.2 patients per station	31.6236
	and subtract the number of certified and pending stations to determine the number of stations needed	3.6236

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed at BMA Fuquay is four stations, based on rounding allowed in Step (v). 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 one new station; therefore, the application is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2019 SMFP which is applicable to this review. Policy GEN-3: Basic Principles, on page 31 of the 2019 SMFP, is applicable to this review because the facility need methodology is applicable to this review. Policy GEN-3 states:

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

Promote Safety and Quality

The applicant describes how it believes the proposed project will promote safety and quality in Section B.3 (a and d), pages 12 and 14, respectively; Section N.2(b), page 59; Section O, pages 61-64; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project will promote equitable access in Section B.3 (b and d), pages 12-13 and 14, respectively; Section C.7, pages 25-26; Section L, pages 53-56; Section N.2(c), page 59; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project will maximize healthcare value in Section B.3 (c and d), pages 13-14; Section N.2(a), page 59; and referenced exhibits. The information provided by the applicant with regard to its efforts to maximize healthcare value is reasonable and supports the determination that the applicant’s proposal will maximize healthcare value.

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

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

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

C

The applicant proposes to add one dialysis station at BMA Fuquay for a total of 29 dialysis stations upon project completion.

The following table, summarized from data on page 7 of the application and Table B of the July 2019 SDR, shows the current and projected number of dialysis stations at BMA Fuquay

BMA Fuquay		
# of Stations	Description	Project ID #
28	Total # of existing certified stations as reported in the SDR in effect on the day the review will begin	
1	# of stations to be added as part of this project	J-11770-19
	# of stations to be deleted as part of this project	
	# of stations previously approved to be added but not yet certified	
	# of stations previously approved to be deleted but not yet certified	
	# of stations proposed to be added in an application still under review	
	# of stations proposed to be deleted in an application still under review	
29	Total # of stations upon completion of all facility projects	

As outlined in the table above, in this application, the applicant proposes to add one dialysis station for a total of 29 stations upon the project completion.

Patient Origin

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.” Thus, the service area for this facility is Wake County. Facilities may serve residents of counties not included in their service area.

In Section C.2, page 17, the applicant provides the patient origin for in-center (IC), home hemodialysis (HH), and peritoneal dialysis (PD) patients at BMA Fuquay as of December 31, 2018, as summarized in the table below.

**BMA Fuquay
 1/1/2018 -12/31/2018**

COUNTY	# IC PATIENTS	% IC Total	# HH Patients	% HH Total	# PD Patients	% PD Total
Wake	75.00	78.9%	6.00	75.0%	25.00	75.8%
Cumberland	0.00	0.0%	0.00	0.0%	1.00	3.0%
Harnett	15.00	15.8%	2.00	25.0%	2.00	6.1%
Johnston	3.00	3.2%	0.00	0.0%	3.00	9.1%
Lee	0.00	0.0%	0.00	0.0%	1.00	3.0%
Sampson	0.00	0.0%	0.00	0.0%	1.00	3.0%
Other States	2.00	2.1%	0.00	0.0%	0.00	0.0%
Total	95.00	100.0%	8.00	100.0%	33.00	100.0%

Totals may not sum due to rounding

The following table summarizes projected patient origin for the second full operating year following project completion, as provided in Section C, page 18

**BMA Fuquay
 Projected Patient Origin
 OY2 CY2022**

COUNTY	# IC PATIENTS	% IC Total	# HH Patients	% HH Total	# PD Patients	% PD Total
Wake	78.60	79.8%	5.66	67.6%	27.20	79.3%
Harnett	14.90	15.2%	2.72	32.4%	4.10	11.9%
Johnston	5.00	5.1%	0.00	0.0%	1.00	2.9%
Lee	0.00	0.0%	0.00	0.0%	1.00	2.9%
Sampson	0.00	0.0%	0.00	0.0%	1.00	2.9%
Total	98.60	100.0%	8.38	100.0%	34.20	100.0%

Totals may not sum due to rounding

In Section C, pages 18-23, the applicant provides the assumptions and methodology it used to project IC, HH, and PD patient origin. The applicant states that the in-center and home therapies patient origin is based upon the June 30, 2019 facility information submitted to the Agency in August 2019 and provided on pages 18 and 21, respectively, of the application. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In-Center Dialysis

The applicant proposes to add one dialysis station for a total of 29 dialysis stations upon project completion.

In Section Q, pages 73-75, the applicant describes its need methodology and assumptions for projecting in-center utilization of the facility, summarized as follows:

- The applicant states that it projects patients forward from the June 30, 2019 census data, which the applicant states was submitted to the Agency on the ESRD Data Collection form in August 2019. The applicant provides a table on page 73 that shows the facility census as of December 31, 2018 and June 30, 2019, as summarized below.

**BMA Fuquay
In-Center Patients**

COUNTY	12/31/2018	6/30/2019
Wake	75	78
Harnett	15	11
Johnston	3	5
Other States	2	0
Total	95	94

- In Project ID J-11510-18, the applicant projected that nine Wake County residents dialyzing at BMA Fuquay would transfer their care to the proposed FKC Holly Springs as of December 31, 2020. Those nine patients will be subtracted from the total Wake County patients as of December 31, 2020.
- The applicant states that it assumes the patients from Wake County dialyzing at BMA Fuquay on June 30, 2019 will continue to dialyze there and will increase at a rate equal to the 3.6% Wake County Five Year Average Annual Change Rate (AACR) published in the July 2019 SDR.
- The applicant states that it assumes the patients from Harnett County dialyzing at BMA Fuquay on June 30, 2019 will continue to dialyze there and will increase at a rate equal to the 9.1% Harnett County Five Year AACR published in the July 2019 SDR. The applicant states this is reasonable because the Fuquay facility is close to the Harnett County line and BMA Fuquay has consistently served a significant number of patients from Harnett County as demonstrated in the table on page 74.
- The applicant assumes the June 30, 2019 patients from Johnston County will continue to dialyze at BMA Fuquay but does not assume any growth in patients from this county.

- Services will be offered as of December 31, 2020. Therefore, Operating Year (OY) 1 is calendar year (CY) 2021, January 1-December 31, 2021 and OY2 is CY2022, January 1-December 31, 2022.

In-Center Projected Utilization

In Section Q, page 75, the applicant provides its projected utilization methodology, based on its stated assumptions. The projected in-center utilization is summarized in the following table.

BMA FUQUAY IN-CENTER PATIENTS

	Wake	Harnett
Begin with facility census of Wake and Harnett county patients as of June 30, 2019.	78	11
Project Wake and Harnett county population forward six months to December 31, 2019, using the Wake County Five Year AACR of 3.6% (3.6% / 12 x 6 = 1.8%) and Harnett County AACR of 9.1% (9.1% / 12 x 6 = 4.55%).	$78 \times 1.018 = 79.4$	$11 \times 1.0455 = 11.5$
Project Wake and Harnett county population forward one year to December 31, 2020, using the Wake County AACR of 3.6% and Harnett County AACR of 9.1%.	$79.4 \times 1.036 = 82.3$	$11.5 \times 1.091 = 12.5$
Subtract nine Wake County patients projected to transfer to FKC Holly Springs (Project ID #J-11510-18)	$82.3 - 9 = 73.3$	$12.5 - 0 = 12.5$
Sum the Wake and Harnett county patients and add the five Johnston County patients. This is the ending census on December 31, 2020.	$73.3 + 12.5 + 5 = 90.8$	
Project the Wake and Harnett county population forward one year to December 31, 2021, using the Wake County AACR of 3.6% and Harnett County AACR of 9.1%.	$73.3 \times 1.036 = 75.9$	$12.5 \times 1.091 = 13.7$
Sum the Wake and Harnett county patients and add the five Johnston County patients. This is the ending census on December 31, 2021.	$75.9 + 13.7 + 5 = 94.6$	
Project Wake and Harnett county population forward one year to December 31, 2021, using the Wake County AACR of 3.6% and Harnett County AACR of 9.1%.	$75.9 \times 1.036 = 78.6$	$13.7 \times 1.091 = 14.9$
Sum the Wake and Harnett county patients and add the five Johnston County patients. This is the ending census on December 31, 2022.	$78.6 + 14.9 + 5 = 98.6$	

Source: Table in Section Q, page 75
 Totals may not sum due to rounding

At the end of OY1 (CY2021) BMA Fuquay is projected to serve 94.6 in-center patients on 29 stations; and at the end of OY2 (CY2022) the facility is projected to serve 98.6 in-center patients on 29 stations.

The projected utilization rates for the first two operating years are as follows:

- OY1: 3.26 patients per station per week, or 81.55% utilization [$94.6 / 29 = 3.315$; $3.262 / 4 = 0.8155$].
- OY 2: 3.4 patients per station per week, or 85.0% utilization [98.6 patients / 29 stations = 3.4 ; $3.4 / 4 = 0.8500$].

The projected utilization of 3.26 patients per station per week at the end of OY1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

Projected utilization is reasonable and adequately supported for the following reasons:

- BMA Fuquay was operating at 84.82% capacity as of December 31, 2018, as reported in the July 2019 SDR.
- The applicant projects growth in the Wake County patient population using the Wake County Five Year AACR of 3.6%, as published in the July 2019 SDR.
- The applicant projects growth in the Harnett County patient population using the Harnett County Five Year AACR of 9.1%, as published in the July 2019 SDR.
- The applicant does not project growth for patients residing outside of Wake and Harnett counties.
- The applicant appropriately reduces the census by the number of Wake County patients transferring their care pursuant to previously approved Project ID #J-11510-18.
- Projected IC utilization at the end of OY1 exceeds the minimum of 3.2 patients per station per week required by 10A NCAC 14C .2203(b).

Home Therapy Projected Utilization

In Section Q, pages 76-78, the applicant makes the following assumptions in the projection of home therapies:

- The applicant states that it projects patients forward from the June 30, 2019 census data, which the applicant states was submitted to the Agency on the ESRD Data Collection form in August 2019. The applicant provides a table on page 76 that shows the facility census as of December 31, 2018 and June 30, 2019, as summarized below.

**BMA Fuquay
 Home Therapy Patients**

COUNTY	DECEMBER 31, 2018		JUNE 30, 2019	
	HH	PD	HH	PD
Wake	6	25	5	24
Cumberland		1		
Harnett	2	2	2	3
Johnston		3		1
Lee		1		1
Sampson		1		1
Other States				
Total	8	33	7	30

As shown in the table above, seven HH patients and 30 PD patients were served at BMA Fuquay as reported on the June 30, 2019 patient origin data submitted to the Agency in August 2019.

- The applicant states that it assumes the patients from Wake County dialyzing at BMA Fuquay on June 30, 2019 will continue to dialyze there and will increase at a rate equal to the 3.6% Wake County Five Year AACR published in the July 2019 SDR.
- The applicant states that it assumes the patients from Harnett County dialyzing at BMA Fuquay on June 30, 2019 will continue to dialyze there and will increase at a rate equal to 9.1% Harnett County Five Year AACR published in the July 2019 SDR. The applicant states this is reasonable because the Fuquay facility is close to the Harnett County line and BMA Fuquay has consistently served a significant number of patients from Harnett County as demonstrated in the table on page 76.
- The applicant assumes the three June 30, 2019 PD patients from outside of Wake and Harnett counties will continue to dialyze at BMA Fuquay but does not assume any growth in patients from these counties.
- Services will be offered as of December 31, 2020. Therefore, Operating Year (OY) 1 is calendar year (CY) 2021, January 1-December 31, 2021 and OY2 is CY2022, January 1-December 31, 2022.

BMA FUQUAY HOME HEMODIALYSIS PATIENTS

	Wake	Harnett
Begin with facility census of Wake and Harnett county patients as of June 30, 2019.	5	2
Project Wake and Harnett county population forward six months to December 31, 2019, using the Wake County Five Year AACR of 3.6% ($3.6\% / 12 \times 6 = 1.8\%$) and Harnett County AACR of 9.1% ($9.1\% / 12 \times 6 = 4.55\%$).	$5 \times 1.018 = 5.09$	$2 \times 1.0455 = 2.09$
Project Wake and Harnett county population forward one year to December 31, 2020, using the Wake County AACR of 3.6% and Harnett County AACR of 9.1%.	$5.09 \times 1.036 = 5.30$	$2.09 \times 1.091 = 2.30$
Sum the Wake and Harnett county patients. This is the ending census on December 31, 2020.	$5.30 + 2.30 = 7.60$	
Project the Wake and Harnett county population forward one year to December 31, 2021, using the Wake County AACR of 3.6% and Harnett County AACR of 9.1%.	$5.3 \times 1.036 = 5.46$	$2.3 \times 1.091 = 2.49$
Sum the Wake and Harnett county patients. This is the ending census on December 31, 2021.	$5.46 + 2.49 = 7.95$	
Project Wake and Harnett county population forward one year to December 31, 2021, using the Wake County AACR of 3.6% and Harnett County AACR of 9.1%.	$5.46 \times 1.036 = 5.66$	$2.49 \times 1.091 = 2.72$
Sum the Wake and Harnett county patients. This is the ending census on December 31, 2022.	$5.66 + 2.72 = 8.38$	

Source: Table in Section Q, page 77
 Totals may not sum due to rounding

BMA FUQUAY PERITONEAL DIALYSIS PATIENTS

	Wake	Harnett
Begin with facility census of Wake and Harnett county patients as of June 30, 2019.	24	3
Project Wake and Harnett county population forward six months to December 31, 2019, using the Wake County Five Year AACR of 3.6% ($3.6\% / 12 \times 6 = 1.8\%$) and Harnett County AACR of 9.1% ($9.1\% / 12 \times 6 = 4.55\%$).	$24 \times 1.018 = 24.43$	$3 \times 1.0455 = 3.14$
Project Wake and Harnett county population forward one year to December 31, 2020, using the Wake County AACR of 3.6% and Harnett County AACR of 9.1%.	$24.43 \times 1.036 = 25.31$	$3.14 \times 1.091 = 3.42$
Sum the Wake and Harnett county patients and add the patients from outside Wake and Harnett counties. This is the ending census on December 31, 2020.	$25.31 + 3.42 + 3 = 31.73$	
Project the Wake and Harnett county population forward one year to December 31, 2021, using the Wake County AACR of 3.6% and Harnett County AACR of 9.1%.	$25.31 \times 1.036 = 26.22$	$3.42 \times 1.091 = 3.73$
Sum the Wake and Harnett county patients and add the patients from outside Wake and Harnett counties. This is the ending census on December 31, 2021.	$26.22 + 3.73 + 3 = 32.96$	
Project Wake and Harnett county population forward one year to December 31, 2021, using the Wake County AACR of 3.6% and Harnett County AACR of 9.1%.	$26.22 \times 1.036 = 27.17$	$3.73 \times 1.091 = 4.07$
Sum the Wake and Harnett county patients and add the patients from outside Wake and Harnett counties. This is the ending census on December 31, 2022.	$27.17 + 4.07 + 3 = 34.24$	

Source: Table in Section Q, page 77
 Totals may not sum due to rounding

At the end of OY1 (CY2021) BMA Fuquay is projected to serve 7.95 HH patients and 32.96 PD patients; and at the end of OY2 (CY2022) the facility is projected to serve 8.38 HH patients and 34.24 PD patients.

Projected utilization of the home training program is reasonable and adequately supported for the following reasons:

- The applicant projects growth in the Wake County home training patient population using the Wake County Five Year AACR of 3.6%, as published in the July 2019 SDR.
- The applicant projects growth in the Harnett County patient population using the Harnett County Five Year AACR of 9.1%, as published in the July 2019 SDR.
- The applicant does not project growth for patients residing outside of Wake and Harnett counties.

The total IC, HH, and PD projected utilization is shown in Section Q, page 78 and summarized below.

**BMA Fuquay
 Projected Patient Utilization**

COUNTY	December 31, 2021			December 31, 2022		
	# IC PATIENTS	# HH Patients	# PD Patients	# IC PATIENTS	# HH Patients	# PD Patients
Wake	75.90	5.46	26.22	78.60	5.66	27.17
Harnett	13.70	2.49	3.73	14.90	2.72	4.07
Johnston	5.00		1.00	5.00		1.00
Lee			1.00			1.00
Sampson			1.00			1.00
Total	94.59	7.95	32.96	98.57	8.38	34.24

Totals may not sum due to rounding

Projected utilization of the total proposed IC, HH, and PD program at BMA Fuquay is reasonable and adequately supported for the reasons stated above.

Access

In Section C.7, pages 25-26, the applicant states:

“Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.

It is corporate policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.

Fresenius related facilities in North Carolina have historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for being an underserved person.”

In Section L, page 55, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as summarized in the following table.

**BMA Fuquay
 Projected Payor Mix CY 2022**

Payment Source	In-Center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	1.47	1.49%	0.00	0.00%	0.00	0.00%
Commercial Insurance*	8.16	8.27%	2.67	31.85%	10.46	30.56%
Medicare*	62.79	63.70%	5.49	65.53%	20.07	58.62%
Medicaid*	2.93	2.97%	0.00	0.00%	0.63	1.83%
Medicare/Commercial	19.15	19.43%	0.22	2.63%	3.08	8.99%
Miscellaneous (Incl. VA)	4.07	4.12%	0.00	0.00%	0.00	0.00%
Total	98.57	100.00%	8.38	100.00%	34.24	100.00%

Totals may not sum due to rounding
 *Including any managed care plans

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

(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

The applicant does not propose a reduction, elimination or relocation of a facility or service; therefore, Criterion (3a) is not applicable to this review.

- (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

The applicant proposes to add one dialysis station at BMA Fuquay for a total of 29 dialysis stations upon project completion.

In Section E, pages 31-33, the applicant states it considered the following alternatives to serve the needs of the patients in the area:

1. Maintain the status quo – the applicant states that this alternative fails to recognize the growth of the ESRD patient population residing in the BMA Fuquay area. The applicant states that failure to add stations will result in higher utilization rates at the facility and fewer opportunities for patient admission.
2. Relocate stations from a BMA facility in Wake County – the applicant lists multiple facilities from which stations could be relocated and states that those Fresenius related facilities are well utilized and relocating stations would leave the facilities short of stations at that location. Additionally, the methodology fails to produce replacement stations at some of the facilities and at the ones where the methodology does produce additional stations, they are needed at the facility. The applicant states that relocating stations from the stated facilities would be inappropriate under the existing circumstances listed with each facility, as discussed on pages 31-33.

On page 33, the applicant states that after considering the above alternatives, it elected to add one station because this proposal is the most cost-effective approach to providing the necessary services for the patient population projected to be served at BMA Fuquay.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provided credible information to explain why it believes the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and

- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Bio-Medical Applications of North Carolina, Inc. shall materially comply with all representations made in the certificate of need application.**
 - 2. Pursuant to the facility need determination in the July 2019 SDR, Bio-Medical Applications of North Carolina, Inc. shall develop no more than one additional dialysis station at BMA Fuquay Varina Kidney Center for a total of no more than 29 certified stations upon completion of this project, which shall include any home hemodialysis training or isolation stations.**
 - 3. Bio-Medical Applications of North Carolina, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to add one dialysis station at BMA Fuquay for a total of 29 dialysis stations upon project completion.

Capital and Working Capital Costs

In Section Q Form F.1a Capital Cost, page 81, the applicant projects the following total capital cost associated with this project.

Medical Equipment	\$750
Furniture	\$3,000
Total Capital Cost	\$3,750

In Section Q, page 82, the applicant provides the assumptions used to project the capital cost.

In Sections F.3, pages 35-36, the applicant states there will be no start-up or initial operating expenses associated with the proposed project since this is an existing facility that is already operational.

Availability of Funds

In Section F.2, page 34, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	Bio-Medical Applications of North Carolina, Inc.	Total
Loans		
Accumulated reserves or OE *	\$3,750	\$3,750
Bonds		
Other (Specify)		
Total Financing	\$3,750	\$3,750

* OE = Owner's Equity

Exhibit F-2 contains a letter dated September 16, 2019 from the Senior Vice President and Treasurer, authorizing and committing accumulated reserves of Fresenius Medical Care Holdings (FMCH), the parent company for BMA, for the capital costs of the project. The letter also documents that the 2018 Consolidated Balance Sheet for FMCH reflects more than \$1.8 billion in cash, and total assets exceeding \$20 billion.

Financial Feasibility

The applicant provides pro forma financial statements for the first two full operating years following completion of the project. In Section Q Form F.2, page 84, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as summarized in the table below.

BMA Fuquay Projected Revenue and Operating Expenses

	OY 1 CY2021	OY 2 CY2022
Total Treatments (IC, HH, and PD)	19,653.99	20,474.22
Total Gross Revenue (charges)	\$123,643,244	\$128,803,349
Total Net Revenue	\$7,133,532	\$7,431,028
Average Net Revenue per Treatment	\$362.96	\$362.95
Total Operating Expenses (costs)	\$4,945,168	\$5,099,748
Average Operating Expense per Treatment	\$251.61	\$249.08
Net Income / Profit	\$2,188,364	\$2,331,279

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs, and charges. See Section Q 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.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
 - The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the proposal.
 - The applicant adequately demonstrates the availability of sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to add one dialysis station at BMA Fuquay for a total of 29 dialysis stations upon project completion.

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining 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 14 dialysis centers in Wake County. Also, BMA has been approved to develop two additional facilities in Wake County, FKC Holly Springs and FMC Rock Quarry, but the facilities were not yet operational on December 31, 2018. DaVita is the only other provider of dialysis services in Wake County, and currently operates Wake Forest Dialysis, and has been approved to develop Oak City Dialysis. See the following table that shows the existing and approved dialysis facilities in Wake County, from Table B of the July 2019 SDR:

Wake County Dialysis Facilities

Dialysis Facility	Certified Stations 12/31/18	CON Issued Not Certified	% Utilization	Patients Per Station
BMA of Fuquay-Varina Kidney Center (BMA)	28	0	84.82%	3.3929
BMA of Raleigh Dialysis (BMA)	50	0	90.50%	3.6200
Cary Kidney Center (BMA)	24	0	89.58%	3.5833
FMC Eastern Wake (BMA)	17	0	64.71%	2.5882
FMC Morrisville (BMA)	10	0	45.00%	1.8000
FMC New Hope Dialysis (BMA)	36	0	86.11%	3.4444
FMC Northern Wake (BMA)	14	0	87.50%	3.5000
Wake Dialysis Clinic (BMA)	50	0	98.50%	3.9400
FKC Holly Springs (BMA)	0	10	NA	NA
FMC Apex (BMA)	20	0	82.50%	3.3000
FMC Central Raleigh (BMA)	19	0	67.11%	2.6842
FMC Millbrook (BMA)	17	0	76.47%	3.0588
FMC Rock Quarry (BMA)	0	10	NA	NA
FMC White Oak (BMA)	12	0	62.50%	2.5000
Oak City Dialysis (DaVita)	0	10	NA	NA
Southwest Wake County Dialysis (BMA)	30	-2	95.00%	3.8000
Wake Forest Dialysis Center (DaVita)	22	-4	98.86%	3.9545
Zebulon Kidney Center (BMA)	30	-4	86.67%	3.4667

Source: July 2019 SDR, Table B.

In Section G, page 40, the applicant provides the Wake County BMA facility utilization for the periods ended December 31, 2018 and June 30, 2019. The applicant states that the June 30, 2019 data was submitted to the Agency on the ESRD Data Collection form in August 2019. In Section G, page 41, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Wake County. The applicant states:

“This is an application to add one dialysis station,[sic] to BMA Fuquay Varina.

The July 2019 SDR does report a surplus of 15 dialysis stations in Wake County. The SDR also reports that the Wake County ESRD Census for December 31, 2018 was 1,388, and that this census was increasing at a rate of 3.6%. The growth of the Wake County ESRD patient population results in a projection of 49.8 new dialysis patients for 2019. If this growth rate is sustained, (and there is no indication that the growth rate will not be sustained), and assuming the home patient population percentage remains the same, Wake County will need 13 new dialysis stations each year (at 80% utilization; 14 new stations at 75% utilization). The current surplus of stations will be quickly eroded.

Approval of this application [sic] not cause unnecessary duplication of services, but will ensure an adequate inventory of dialysis stations exists for the ESRD patient population of the county.”

The applicant adequately demonstrates that the proposal will not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- There is a facility need determination at BMA Fuquay, as calculated using the methodology in the July 2019 SDR, for the proposed additional dialysis station.
- The applicant adequately demonstrates that the proposed dialysis station is needed in addition to the existing or approved additional dialysis stations.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

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

C

In Section Q Form H Staffing, page 92, the applicant provides a table showing current and projected staffing in full time equivalent (FTE) positions for BMA Fuquay, as summarized below.

POSITION	FTE Positions as of 6/30/19	FTE POSITIONS OY1	FTE POSITIONS OY2
FMC Clinic Manager	1.00	1.00	1.00
RN	4.00	4.00	4.00
Home Training RN	3.00	3.00	3.00
Patient Care Technician	9.50	10.50	10.50
Dietician	1.00	1.00	1.00
Social Worker	1.00	1.00	1.00
Equipment Technician	1.00	1.00	1.00
Administration	1.00	1.00	1.00
FMC Director Operations	0.15	0.15	0.15
In-Service	0.20	0.20	0.20
Chief Technician	0.20	0.20	0.20
Total	22.05	23.05	23.05

Source: Section Q Form H

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.4 Operating Costs. In Section H, page 43, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. Exhibit H contains documentation of its continuing education programs. In Section H.4, page 44, the applicant identifies the current medical director for the facility as Dr. Godwin. In Exhibit H-4, the applicant provides a letter from James Godwin, MD indicating his intent to continue to serve as medical director for the proposed services.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

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

C

In Section I, page 46, the applicant states that the following ancillary and support services are necessary for the proposed services, and explains how each ancillary and support service is made available:

ANCILLARY AND SUPPORT SERVICES	
SERVICES	PROVIDER
Self-care training	BMA on site
Home training HH PD Accessible follow-up program	BMA on site
Psychological counseling	Referral to Carolina Partners in Mental Health or Best Day Psychiatry and Counseling
Isolation – hepatitis	BMA on site
Nutritional counseling	BMA on site
Social Work services	BMA on site
Acute dialysis in an acute care setting	Referral to WakeMed, Rex Hospital, or Duke Health Raleigh
Emergency care	BMA staff until ambulance transport to hospital
Blood bank services	Referral to Red Cross
Diagnostic and evaluation services	Referral to Wake Radiology
X-ray services	Referral to Wake Radiology
Laboratory services	BMA on site / Spectra
Pediatric nephrology	Referral to UNC Healthcare
Vascular surgery	Referral to Rex Hospital; Raleigh Access Center; WakeMed Vascular
Transplantation services	Referral to UNC Healthcare
Vocational rehabilitation & counseling	Referral to Wake County Vocational Rehabilitation
Transportation	Go Cary, or Go Wake transportation services

Source: Table in Section I, page 46

In Section I, page 46, the applicant describes its existing and proposed relationships with other local health care and social service providers. In Exhibit I, the applicant provides supporting documentation for established relationships with local health care providers and for referrals.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that 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

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (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

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (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

The applicant does not propose any construction or renovation with this project. Therefore, Criterion (12) is not applicable to this review.

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

C

In Section L, page 54, the applicant provides the historical payor mix for BMA Fuquay patients during CY2018 for its existing services, as shown in the table below.

**BMA Fuquay
 Historical Payor Mix CY2018**

Payment Source	In-Center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	1.42	1.49%	0.00	0.00%	0.00	0.00%
Commercial Insurance*	7.86	8.27%	2.55	31.85%	10.08	30.56%
Medicare*	60.52	63.70%	5.24	65.53%	19.35	58.62%
Medicaid*	2.83	2.97%	0.00	0.00%	0.60	1.83%
Medicare/Commercial	18.46	19.43%	0.21	2.63%	2.97	8.99%
Miscellaneous (Incl. VA)	3.92	4.12%	0.00	0.00%	0.00	0.00%
Total	95.00	100.00%	8.00	100.00%	33.00	100.00%

Totals may not sum due to rounding

*Including any managed care plans

In Section L.1(a), page 53, the applicant provides comparison of the demographical information on BMA Fuquay patients and the service area patients during CY2018, as summarized below.

	Percentage of Total Patients Served during the Last Full OY	Percentage of the Population of the Service Area*
Female	39.8%	51.3%
Male	60.2%	48.7%
Unknown		
64 and Younger	54.9%	88.4%
65 and Older	45.1%	11.6%
American Indian	0.0%	0.8%
Asian	6.0%	7.5%
Black or African-American	51.1%	21.0%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	40.6%	59.8%
Other Race	2.3%	10.8%
Declined / Unavailable	0.0%	

* The percentages can be found online using the United States Census Bureau's QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>. Just enter in the name of the county.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the applicant adequately documents 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. 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

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, the applicant states in Section L, page 54, that it has no obligation in any of its facilities to provide uncompensated care, community service, or access by minorities and handicapped persons.

In Section L, page 55, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section L, page 55, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as summarized in the following table.

**BMA Fuquay
 Projected Payor Mix CY 2022**

Payor Source	In-Center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	1.47	1.49%	0.00	0.00%	0.00	0.00%
Commercial Insurance*	8.16	8.27%	2.67	31.85%	10.46	30.56%
Medicare*	62.79	63.70%	5.49	65.53%	20.07	58.62%
Medicaid*	2.93	2.97%	0.00	0.00%	0.63	1.83%
Medicare/Commercial	19.15	19.43%	0.22	2.63%	3.08	8.99%
Miscellaneous (Incl. VA)	4.07	4.12%	0.00	0.00%	0.00	0.00%
Total	98.57	100.00%	8.38	100.00%	34.24	100.00%

Totals may not sum due to rounding

*Including any managed care plans

As shown in the table above, in the second full year of operation, the applicant projects that 1.49% of in-center dialysis services will be provided to self-pay patients, 83.13% to Medicare patients (includes Medicare and Medicare/Commercial), and 2.97% to Medicaid patients. Relatively, the same percentages for Medicare payors are projected for the home training program; however, commercial insurance is projected to provide just over 30% of the reimbursement for the home training program, with a lower percent provided by Medicaid, as compared to in-center services.

On page 55, the applicant provides the assumptions and methodology it uses to project payor mix during the second full year of operation following completion of the project, stating the payor mix is based upon recent facility history of actual treatment volumes. The applicant explains that Fresenius reports payor source of treatments, not whole

patients as requested in the table, which the applicant states provides a clear indication of the source of revenue.

The projected payor mix is reasonable and adequately supported because the projected payor mix is based on the historical payor mix of BMA Fuquay.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that 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, page 56, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that 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, page 57, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.

- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to add one dialysis station at BMA Fuquay for a total of 29 dialysis stations upon project completion.

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining 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 14 dialysis centers in Wake County. Also, BMA has been approved to develop two additional facilities in Wake County, FKC Holly Springs and FMC Rock Quarry but the facilities were not yet operational on December 31, 2018. DaVita is the only other provider of dialysis services in Wake County, and currently operates Wake Forest Dialysis, and has been approved to develop Oak City Dialysis. See the following table that shows the existing and approved dialysis facilities in Wake County, from Table B of the July 2019 SDR:

Wake County Dialysis Facilities

Dialysis Facility	Certified Stations 12/31/18	CON Issued Not Certified	% Utilization	Patients Per Station
BMA of Fuquay-Varina Kidney Center (BMA)	28	0	84.82%	3.3929
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FMC Eastern Wake (BMA)	17	0	64.71%	2.5882
FMC Morrisville (BMA)	10	0	45.00%	1.8000
FMC New Hope Dialysis (BMA)	36	0	86.11%	3.4444
FMC Northern Wake (BMA)	14	0	87.50%	3.5000
Wake Dialysis Clinic (BMA)	50	0	98.50%	3.9400
FKC Holly Springs (BMA)	0	10	NA	NA
FMC Apex (BMA)	20	0	82.50%	3.3000
FMC Central Raleigh (BMA)	19	0	67.11%	2.6842
FMC Millbrook (BMA)	17	0	76.47%	3.0588
FMC Rock Quarry (BMA)	0	10	NA	NA
FMC White Oak (BMA)	12	0	62.50%	2.5000
Oak City Dialysis (DaVita)	0	10	NA	NA
Southwest Wake County Dialysis (BMA)	30	-2	95.00%	3.8000
Wake Forest Dialysis Center (DaVita)	22	-4	98.86%	3.9545
Zebulon Kidney Center (BMA)	30	-4	86.67%	3.4667

Source: July 2019 SDR, Table B.

According to Table D in the July 2019 SDR, there is a surplus of 15 dialysis stations in Wake County. The applicant proposes to add one dialysis station to the existing facility in Wake County pursuant to the facility need determination methodology.

In Section N, pages 58-60, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality, and access to the proposed services. The applicant states:

“The applicant does not expect this proposal to have any effect on the competitive climate in Wake County. The applicant does not project to serve dialysis patients currently being served by another provider. The projected patient population for the BMA Fuquay Varina facility begins the current patient population.

...

Fresenius related facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid.

...

Fresenius related facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients.

...

Fresenius Medical Care, parent organization for this facility, expects every facility to provide high quality care to every patient at every treatment.

...

It is corporate policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.”

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections B, F, and Q of the application and any exhibits).
- Quality services will be provided (see Sections B and O of the application and any exhibits).
- Access will be provided to underserved groups (see Sections B and L of the application and any exhibits).

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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 Section Q Form A Facilities, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies 127 dialysis facilities owned, operated, or managed by the applicant or a related entity located in North Carolina.

In Section O, page 64, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care that resulted in a finding

of “*Immediate Jeopardy*” occurred in any of these facilities. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all Fresenius facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

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

C

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

10 NCAC 14C .2203 PERFORMANCE STANDARDS

(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 is an existing facility.

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

-C- In Section Q Form C, page 72, the applicant projects that BMA Fuquay will serve 94.6 in-center patients on 29 stations, or a rate of 3.26 patients per station per week, as of the end of the first operating year following project completion. This exceeds the minimum performance standard of 3.2 patients per station per week.

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

- C- In Section Q, pages 73-78, the applicant provides the assumptions and methodology it used to project utilization of the facility.