ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

Decision Date:	February 12, 2019
Findings Date:	February 12, 2019
Project Analyst:	Celia C. Inman
Team Leader:	Fatimah Wilson
Project ID #:	J-11575-18
Facility:	BMA of Raleigh Dialysis
FID #:	956008
County:	Wake
Applicant:	Bio-Medical Applications of North Carolina, Inc.
Project:	Add no more than four dialysis stations to BMA of Raleigh for a total of no more than 50 dialysis stations upon completion of this project and CON Project ID # J-11510-18 (relocate four stations to FKC Holly Springs)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. § 131E-183(a) The Department 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. (BMA), the applicant, currently operates a 50-station dialysis facility located at 3943 New Bern Avenue, Raleigh, Wake County. The applicant proposes to add four dialysis stations to its existing facility for a total of 50 stations at BMA of Raleigh Dialysis (BMA Raleigh) upon completion of this project and Project ID #J-11510-18 (relocate four stations to FKC Holly Springs).

Need Determination

The 2018 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to

Table D in the July 2018 Semiannual Dialysis Report (SDR), there is a surplus of 11 dialysis 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 stations based on the facility need methodology because the utilization rate reported for BMA Raleigh in the July 2018 SDR is 3.66 patients per station per week. This utilization rate was calculated based on 183 in-center dialysis patients and 50 certified dialysis stations. (183 patients / 50 stations = 3.66 patients per station). The facility need methodology requires a facility's utilization rate in the latest SDR at the time the application was submitted to be at least 3.2 patients per station per week to be eligible to apply for additional stations based on facility need.

Application of the facility need methodology indicates that up to a potential maximum of twelve additional stations are needed for this facility, as illustrated in the following table.

OCTOBER 1 REVIEW-JULY 2018 SDR		
Required SDR Utilization		80.0%
Center Utilization Rate as of 12/31/17		91.5%
Certified Stations		50
Pending Stations*		0
Total Existing and Pending Stations*		**50**
In-Center Patients as of 12/31/17 (July 2018 SDR) (SDR2)		183
In-Center Patients as of 6/30/17 (Jan 2018 SDR) (SDR1)		176
Step	**Description**	**Result**
(i)	Difference (SDR2 – SDR1)	7
	Multiply the difference by 2 for the projected net in-center change	14
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/17	0.079545
(ii)	Divide the result of Step (i) by 12	0.006629
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/16 until 12/31/17)	0.079545
(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	197.5568
(v)	Divide the result of Step (iv) by 3.2 patients per station	61.7365
	and subtract the number of certified and pending stations to determine the number of stations needed	11.7365

*The table on page 6 shows six pending stations and a total of 56 existing and pending stations resulting in a need for 5.7 stations. This is inaccurate. Pending stations is 0 and total existing and pending stations is 50, resulting in a potential need for 11.7 stations (rounded to 12), as shown above. Here and in several other areas of the application are typographical errors, where the applicant inadvertently uses information from the FMC New Hope application, Project ID #J-11572-18, another Wake County application submitted on the same date. The typographical errors do not impact the review of this application.

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is twelve stations. The facility need methodology allows for rounding in Step (2)b.(v), with fractions of 0.5000 or greater being rounded to the next highest whole number and fractions less than 0.5000 being rounded down to the whole number. The applicant proposes to add four stations. Therefore, the facility need determination for dialysis stations is applicable to this review.

In summary, the application is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2018 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."*

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section B.4 (a and d), pages 8 and 10-11, respectively; Section O, pages 56-59; 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 and d), pages 8-9 and 10-11, respectively; and Section L, pages 48-49. 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 9-11, and Section N, pages 54-55. 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. 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 four dialysis stations to its existing facility for a total of 50 stations at BMA Raleigh upon completion of this project and Project ID #J-11510-18 (relocate four stations to FKC Holly Springs for a total of 46 stations at BMA Raleigh).

The following table, summarizes the information provided by the applicant on page 4 of the application and illustrates the current and projected number of dialysis stations at BMA Raleigh. The July 2018 SDR shows 50 certified dialysis stations at BMA Raleigh, as of December 31, 2017.

Stations	Description	Project ID #
50	Total existing certified stations as of the January 2018 SDR	
+4	Stations to be added as part of this project	J-11575-18
-4	Stations previously approved to be relocated to FKC Holly Springs	J-11510-18
50	Total stations upon completion of proposed project	

Patient Origin

On page 365, the 2018 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."* BMA Raleigh is located in Wake County; thus, the service area for this facility consists of Wake County. Facilities may also serve residents of counties not included in their service area.

In Section C. 8, page 18, the applicant provides the historical patient origin for BMA Raleigh in-center (IC), home hemodialysis (HH) and peritoneal dialysis (PD) patients, as of June 30, 2018, as summarized in the following table.

County	# IC Patients	# HH Patients	# PD Patients
Wake	183	0	46
Johnston	1	0	5
Nash	1	0	0
Total	**185**	**0**	**51**

Source: ESRD Data Collection Forms, as of June 30, 2018, as identified in this table.

In Section C. 1, page 13, the applicant provides the projected patient origin for BMA Raleigh patients for the first two operating years following completion of the project, as summarized in the following table.

County	OY1 CY2020		OY2 CY2021		County Patients as a % of Total	
	In-Center Patients	PD Patients	In-Center Patients	PD Patients	OY1	OY2
Wake	189.7	51.1	197.8	53.3	97.2% [97.5%]	97.3%
Johnston	1.0	5.0	1.0	5.0	2.4%	2.3%
Nash	1.0	0.0	1.0	0.0	0.4%	0.4%
Total*	**191.0**	**56.0**	**199.0**	**58.0**	**100.0%**	**100.0%**

*the applicant rounds down to the whole patient

The applicant does not propose to serve home hemodialysis patients and states on page 39 that patients who are candidates for home hemodialysis are referred to FMC New Hope.

In Section C, pages 13-14, the applicant provides the assumptions and methodology used to project patient origin. The applicant begins future patient projections with the facility census as of June 30, 2018 and assumes utilization will increase by the Wake County five-year Average Annual Change Rate (AACR) of 4.3%, as published in the July 2018 SDR. The applicant assumes that the two patients from Johnston and Nash counties are dialyzing at BMA Raleigh by patient choice and will continue to do so, but the utilization will not increase. The applicant states the methodology includes the three patients expected to transfer their care to FMC White Oak, as of August 2018 (Project ID #J-11220-16); eight patients expected to transfer their care to FMC Rock Quarry, effective December 2019 (Project ID #J-11271-16); and the relocation for four stations and transfer of two patients to FKC Holly springs, effective December 2019 (Project ID #J-11510-18).

The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.2, page 16, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

"The need of this population for the proposed services is a function of the individual patient need for dialysis care and treatment."

Section B.2, page 6, includes the ESRD facility need methodology table which shows a need for up to 12 additional dialysis stations at BMA Raleigh.

The information is reasonable and adequately supported for the following reasons:

- the applicant begins its projections of the patient population to be served with the BMA Raleigh existing patients, as of June 30, 2018,
- the applicant grows the patient population by the July 2018 SDR Wake County five-year average annual change rate (AACR) of 4.3%,
- the applicant adjusts its utilization to include relocation of stations and transfer of patients as committed in prior applications, and
- the utilization rate of the patients projected to be dialyzing at BMA Raleigh by the end of the first year is above 3.2 patients per station per week.

Projected Utilization

In-Center Dialysis Patients

In Section C, pages 14-15, the applicant provides the assumptions and methodology used to project utilization, as summarized below:

BMA of Raleigh Dialysis	In-Center
Begin with the historical utilization of 183 in-center Wake County dialysis patients as of June 30, 2018.	183
Project the Wake County patient population forward six months to December 31, 2018, using the AACR of 4.3% (.043/12*6=0.0215)	183 x 1.0215 = 186.9
Subtract three Wake County patients who expressed desire to transfer to FMC White Oak	186.9 - 3 = 183.9
Project the Wake County patient population forward one year to December 31, 2019, using the AACR of 4.3%	183.9 x 1.043 =191.8
Subtract eight Wake County patients who expressed desire to transfer to FMC Rock Quarry and two patients transferring to FKC Holly Springs	191.8 - 10 = 181.8
Add the two patients from Johnston and Nash Counties. This is the starting census for the project at January 1, 2020.	181.8 + 2 = 183.8
Project the Wake County patient population forward one year to December 31, 2020, using the AACR of 4.3%	181.8 x 1.043 = 189.7
Add the two patients from Johnston and Nash Counties. This is the end of Operating Year 1	189.7 + 2 = 191.7
Project the Wake County patient population forward one year to December 31, 2021.	189.7 x 1.043 = 197.8
Add the two patients from Johnston and Nash Counties. This is the end of OY2 census.	197.8 + 2 = 199.8

The assumptions for the above projected utilization, pages 13-14, is summarized below:

- Beginning census, June 30, 2018, as reported by the applicant in the ESRD Data Collection Forms submitted to DHSR Healthcare Planning and Certificate of Need Section in August 2018.
- OY1 is the period from January 1 through December 31, 2020.
- OY2 is the period from January 1 through December 31, 2021.
- The 183 patients from Wake County and the two patients from Johnston and Nash counties will continue to dialyze at BMA Raleigh.
- Three Wake County patients will transfer to FMC White Oak (Project ID #J-11220-16), as of December 31, 2018.
- Eight Wake County patients will transfer to FMC Rock Quarry (Project ID #J-11271-16), as of December 31, 2019.
- Four stations will be relocated to FKC Holly Springs and two Wake County patients will transfer to FKC Holly Springs (Project ID #J-11510-18), as of December 31, 2019.
- The Wake County patients will grow at the Wake County AACR of 4.3%, as reported in the July 2018 SDR, and the utilization of the Johnston and Nash county patients will be held constant.

- The applicant rounds down to the whole patient.

Therefore, based on the methodology and assumptions above, the applicant projects that at the end of OY1, 191 patients will be dialyzing on 50 stations for a projected utilization rate of 3.82 patients per station per week (191 in-center patients / 50 stations = 3.82) which exceeds the minimum standard of 3.2 patients per station per week as required by 10A NCAC 14C.2203(b).

The applicant's PD utilization methodology, based on its stated assumptions, is provided on page 15 and is summarized in the following table.

BMA of Raleigh Dialysis	PD Patients
Begin with the historical utilization of Wake County PD patients as of June 30, 2018.	46
Project the Wake County patient population forward six months to December 31, 2018, using the AACR of 4.3% (.043/12*6=0.0215)	46 x 1.0218[5] = 47
Project the Wake County patient population forward one year to December 31, 2019, using the AACR of 4.3%	47 x 1.043 = 49.0
Add five out of county patients. This is the starting census for this project.	49.0 + 5 = 54.0
Project the Wake County patient population forward one year to December 31, 2020, using the AACR of 4.3%	49.0 x 1.043 = 51.1
Add five out of county patients. This is the ending census for operating year one.	51.1 + 5 = 56.1
Project the Wake County patient population forward one year to December 31, 2021.	51.1 x 1.043 = 53.3
Add five out of county patients. This is the ending census for operating year two.	53.3 + 5 = 58.3

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

- the applicant begins its utilization projection with the existing patients of BMA Raleigh,
- the applicant grows the Wake County patient population by the July 2018 SDR Wake County AACR and holds the patient population from outside Wake County constant,
- the applicant deducts the Wake County patients who expressed a desire to transfer their in-center care to other BMA facilities,
- the applicant deducts the four stations being relocated to FKC Holly Springs, and
- the resulting utilization rate at BMA Raleigh by the end of the first year exceeds the minimum standard of 3.2 patients per station per week.

Access

In Section C.3, page 16, the applicant states:

> *"BMA has a long history of providing dialysis services to the underserved populations of North Carolina. Fresenius Medical Care Holdings, Inc. parent company to BMA, currently operates 114 facilities in 48 North Carolina Counties (includes our affiliations with RRI facilities); in addition, BMA has several facilities under development or pending CON approval. 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."*

The applicant projects the payor mix in Section L.1(b), page 49, as summarized below.

Projected Payor Mix
OY2 / CY2021

Payor Source	% of Total Patients	% In-center Patients	% PD Patients
Self Pay/Indigent/Charity	3.49%	3.67%	2.60%
Medicare	50.78%	50.29%	53.27%
Medicaid	6.20%	6.90%	4.03%
Commercial Insurance	12.40%	7.87%	27.56%
Medicare / Commercial	25.97%	29.96%	12.12%
Medicare / Medicaid	0.00%	0.00%	0.00%
Misc. (including VA)	1.16%	1.61%	0.41%
Other	0.00%	0.00%	0.00%
Total	**100.00%**	**100.00%**	**100.00%**

Totals may not sum due to rounding

The applicant states that the projected payor mix is based on facility performance for the 12 months ended June 30, 2018. 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 proposed project does not involve the reduction or elimination of a service or the relocation of a facility or a 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 four dialysis stations to its existing facility for a total of 50 stations at BMA Raleigh upon completion of this project and Project ID #J-11510-18 (relocate four stations to FKC Holly Springs for a total of 46 at BMA Raleigh).

In Section E.1, page 22, the applicant states that it has limited options for expanding access at BMA Raleigh, describes the alternatives considered, and explains why each alternative is either more costly or less effective than the alternative proposed in this application. The alternatives considered prior to the submission of this application are summarized as follows:

1. Maintain the status quo
2. Apply for more stations
3. Relocate stations from one of the existing BMA facilities in Wake County

Thus, after considering the above alternatives, the applicant concludes that its proposal to add four dialysis stations at BMA Raleigh through the facility need methodology, as proposed, is the most effective alternative because it meets the identified need for additional stations at the facility while incurring no capital costs.

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

- the facility is operating at above 80% capacity,
- the facility need methodology indicates a need for additional stations at the facility,
- maintaining the status quo does not address the need for additional stations at the facility and will result in higher utilization rates and potentially restrict patient admissions,
- applying for more than four stations would not be appropriate based on the facility physical plant being limited to 50 stations, and
- relocation of stations from other BMA facilities in Wake County would result in higher utilization levels at those facilities, when as of June 30, 2018, the BMA Wake County facilities averaged 84.22% utilization or 3.37 patients per station per week (page 22 of the application).

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. 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 2018 SDR, Bio-Medical Applications of North Carolina, Inc. shall develop no more than four additional dialysis stations for a total of no more than 50 certified stations at BMA of Raleigh Dialysis upon completion of this project and Project ID #J-11510-18 (relocate four stations to FKC Holly Springs), 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 four dialysis stations to its existing facility for a total of 50 stations at BMA Raleigh upon completion of this project and Project ID #J-11510-18 (relocate four stations to FKC Holly Springs for a total of 46 at BMA Raleigh).

Capital and Working Capital Costs

In Section F.1, page 23, the applicant states that BMA will not incur any capital costs for this project. The proposed additional stations are intended to replace four stations planned for relocation to the FKC Holly Springs facility. The space already exists and the dialysis equipment will be leased.

In Sections F.10 and F.11, page 27, the applicant states that BMA Raleigh is an existing facility, thus the project will not involve start-up or initial operating expenses.

Financial Feasibility

The applicant provides pro forma financial statements for the first two full fiscal years of the project. In Section R, Form B, Revenue and Expense Statement, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

	Operating Year 1 CY2020	**Operating Year 2 CY2021**
Total Average In-Center Patients*	187	195
Total Average PD Patients*	55	57
Total Treatments	35,864	37,346
Total Gross Revenues (Charges)	$143,025,632	$148,935,848
Adjustments from Gross	$131,376,094	$136,811,391
Total Net Revenue	$11,649,538	$12,124,457
Average Net Revenue per Treatment	$325	$325
Total Operating Expenses (Costs)	$8,077,020	$8,337,450
Average Operating Expense per Treatment	$225	$223
Net Income	$3,572,518	$3,787,006

Totals may not sum due to rounding
*Patient census for the year is an average of the beginning and ending patient census, rounded down, per the applicant's assumptions, which differs from the number of patients at the end of the period as shown on the applicant's Form A and Form B.

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section R 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 sufficient operating funds for the operating needs of the proposal, and
- the applicant adequately demonstrates 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 four dialysis stations to its existing facility for a total of 50 stations at BMA Raleigh upon completion of this project and Project ID #J-11510-18 (relocate four stations to FKC Holly Springs for a total of 46 at BMA Raleigh).

On page 365, the 2018 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."* BMA Raleigh is located in Wake County; thus, the service area for this facility consists of Wake County. Facilities may also serve residents of counties not included in their service area.

According to the July 2018 SDR, Wake County has the following existing dialysis facilities operated by Fresenius Medical Care (FMC) and Davita.

Wake County Dialysis Facilities

Facility Name	Provider	Location	#of stations	Utilization
BMA of Fuquay-Varina Kidney Center	FMC	Fuquay-Varina	28	77.68%
BMA Raleigh Dialysis	FMC	Raleigh	50	91.50%
Cary Kidney Center	FMC	Cary	28	79.46%
FMC Apex	FMC	Apex	20	77.50%
FMC Central Raleigh	FMC	Raleigh	19	82.89%
FMC Eastern Wake	FMC	Rolesville	17	72.06%
FMC Millbrook	FMC	Raleigh	17	75.00%
FMC New Hope Dialysis	FMC	Raleigh	36	94.44%
FMC Northern Wake	FMC	Wake Forest	16	65.63%
Southwest Wake County Dialysis	FMC	Raleigh	30	97.50%
Wake Dialysis Clinic	FMC	Raleigh	50	94.50%
Wake Forest Dialysis Center	DaVita	Raleigh	22	94.32%
Zebulon Kidney Center	FMC	Zebulon	28	89.29%

Source: July 2018 SDR, Table B.

FMC related entities own and operate twelve of the 13 existing dialysis facilities in Wake County. The table shows that with the exception of one facility, the existing 13 Wake County facilities are all operating at above 72% capacity. In addition to the existing facilities listed above, the July 2018 SDR includes additional approved facilities consisting of relocated existing stations from facilities listed above. On page 22, the applicant states that the BMA facilities in Wake County averaged 84.22% (3.37 patients per station per week) utilization, as of June 30, 2018.

In Section G, the applicant explains why it believes the proposal would not result in the unnecessary duplication of existing or approved dialysis services in Wake County. The applicant provides a map on page 33 and states on page 33:

> *"As the map demonstrates, the existing facilities in Wake County are widely dispersed across the county. The dialysis facilities have been developed in areas associated with dialysis patient populations."*

In this application, the applicant is proposing to add four stations based on facility need and demonstrates the facility was serving 183 patients weekly on 50 stations, which is 3.66 patients per station per week or 91.5% of capacity, as of June 30, 2018. The applicant does not propose to establish a new facility.

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

- the applicant demonstrates the need for the stations based on the facility need methodology,
- the applicant demonstrates that, other than one FMC facility, the operational facilities owned or operated by the applicant are operating above 72% utilization, and

- the applicant adequately demonstrates that the proposed stations are needed in addition to the existing or approved stations in Wake 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 application is conforming to this criterion for all 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

The applicant proposes to add four dialysis stations to its existing facility for a total of 50 stations at BMA Raleigh upon completion of this project and Project ID #J-11510-18 (relocate four stations to FKC Holly Springs for a total of 46 at BMA Raleigh).

In Section H.1, page 34, the applicant provides the current and projected OY2 staffing for BMA Raleigh by full-time equivalent (FTE) positions, as summarized in the table below:

BMA of Raleigh FTE Positions		
Position	**Current FTE Positions**	**Total OY2 FTE Positions**
Registered Nurse	13.00	13.00
Home Training Nurse	1.00	1.00
LPN	1.00	1.00
Patient Care Technician	18.00	18.00
Dietitian	3.00	3.00
Social Worker	3.00	3.00
Clinical Manager	1.00	1.00
Administrator	0.15	0.15
In-Service	0.33	0.33
Clerical	3.00	3.00
Chief Tech	0.25	0.25
Equipment Tech	1.75	1.75
Total FTEs	**45.48**	**45.48**

The Medical Director is not a salaried employee. Medical Records is included in the Clerical position. The assumptions and methodology used to project staffing are provided in Sections H and R. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in the pro forma financials found in Section R, except for the 1.0 FTE LPN position at $45,457 in OY2. The $3.8 million in net income during OY2 more than covers the omission of the LPN salary. In Exhibit I.5, the applicant provides a letter from Eric Raasch, MD, dated September 10, 2018, indicating support for the project and a willingness to continue to serve as Medical Director of the facility. Dr. Raasch's curriculum vitae is included in Exhibit I-6. In Section H.3, page 35, the applicant states it does not anticipate any difficulties in filling staff positions as it will use aggressive recruiting and advertising efforts, coupled with competitive salaries to attract qualified staff.

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 all 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

The applicant proposes to add four dialysis stations to its existing facility for a total of 50 stations at BMA Raleigh upon completion of this project and Project ID #J-11510-18 (relocate four stations to FKC Holly Springs for a total of 46 at BMA Raleigh).

In Section I.1, the applicant identifies the necessary ancillary and support services and explains how they will be made available. The applicant provides a table on page 38, as summarized below.

BMA of Raleigh
Ancillary and Support Services

Services	Provider
(a) In-center dialysis/maintenance	On Premises
(b)Self-care training (performed in-center)	On Premises
(c) Home training	
(1) Hemodialysis	FMC New Hope Referral
(2) Peritoneal dialysis	On Premises
(3) Accessible follow-up program	On Premises
(d) Psychological counseling	Referral to Wake County mental Health or Carolina Partners
(e) Isolation-hepatitis	On Premises
(f) Nutritional counseling	On Premises
(g) Social work services	On Premises
(h) Acute dialysis in an acute care setting	WakeMed
(i) Emergency care	On Premises/ Emergency Transport to WakeMed
(j) Blood bank services	WakeMed
(k) Diagnostic and evaluation services	WakeMed
(l) X-ray services	WakeMed
(m) Laboratory services	Spectra
(n) Pediatric nephrology	University of North Carolina Hospitals (UNC)
(o) Vascular surgery	Rex Vascular, Wake Vascular, Triangle Interventional, or Raleigh Access Center
(p) Transplantation services	Referral to Duke
(q) Vocational rehabilitation counseling & services	Vocational Rehabilitation of Wake County
(r) Transportation	Wake County Transportation Services, TRACS, ART (Go Raleigh),

In Section I, pages 39-40, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.

The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system.

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 proposed project does not involve construction of new space or renovation. 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.7, page 52, the applicant reports that 84.92% of the patients who received treatments at BMA Raleigh had some or all of their services paid for by Medicare or Medicaid in CY2017. The table below shows the historical (CY2017) payment sources for the facility.

Payor Mix, CY2017

Payment Source	Patients by Percent of Total
Self Pay/Indigent/Charity	3.26%
Medicare	54.93%
Medicaid	5.92%
Commercial Insurance	10.56%
Medicare/Commercial	24.07%
Miscellaneous (including VA)	1.26%
Total	**100.00%**

Totals may not sum due to rounding

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

Percent of Population						
County	**% 65+**	**% Female**	**% Racial and Ethnic Minority***	**% Persons in Poverty****	**% < Age 65 with a Disability**	**% < Age 65 without Health Insurance****
2017 Estimate	**2017 Estimate**	**2017 Estimate**	**2017 Estimate**	**2017 Estimate**	**2017 Estimate**	**2017 Estimate**
Wake	11%	51%	40%	9%	6%	9%
Statewide	16%	51%	37%	15%	10%	12%

Source: http://www.census.gov/quickfacts/table/US/PST045217 *Latest Data 7/1/17 as of 7/17/18*

* *Excludes "White alone, not Hispanic or Latino"*

** *"Estimates are not comparable to other geographic levels due to methodology differences that may exist between different data sources. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable…The vintage year (e.g., V2017) refers to the final year of the series (2010 thru 2017). Different vintage years of estimates are not comparable."*

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consisting of North Carolina, South Carolina and Georgia, provides an Annual Report which includes aggregate ESRD patient data from all three states. The 2016 Annual Report does not provide state-specific ESRD patient data, but the aggregate data is likely to be similar to North Carolina's based on the Network's recent annual reports which included state-specific data.

The IPRO SA Network 6 2016 Annual Report (pages 25-26[1]) provides the following prevalence data on dialysis patients by age, race, and gender. As of December 31, 2016, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 66% were other than Caucasian and 45% were female.

[1] https://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/07/NW6-2016-Annual-Report-FINAL.pdf

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, in Section L.3(d), page 51, the applicant states:

> *"BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations. The facility will be responsible to provide care to both minorities and handicapped people. The applicant will treat all patients the same regardless of race or handicap status. In accepting payments from Medicare, Title XVIII of the Social Security Act, and Medicaid, Title XIX, all BMA North Carolina Facilities are obligated to meet federal requirements of the Civil Rights Act, Title VI and the Americans with Disabilities."*

In Section L.6, page 51, the applicant states that no civil rights complaints have been lodged against any BMA North Carolina facilities in the past five years.

The applicant adequately demonstrates its past performance in meeting its obligations, 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.

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.1(b), page 49, the applicant provides the projected payor mix for the BMA Raleigh facility as summarized in the table below:

Projected Payor Mix
Project Year 2

Payment Source	Patients by Percent of Total
Self Pay/Indigent/Charity	3.49%
Medicare	50.78%
Medicaid	6.20%
Commercial Insurance	12.40%
Medicare/Commercial	25.97%
Miscellaneous (including VA)	1.16%
Total	**100.00%**

Totals may not sum due to rounding

As shown in the table above, the applicant projects 83% of the total patients projected to receive treatments at BMA Raleigh will have some or all of their services paid for by Medicare or Medicaid. The projected payor mix is reasonably comparable to the 2017 payor mix for BMA Raleigh. The applicant states that the projected payor mix is based on the facility's experience during the 12 months ended June 30, 2018. The projected payor mix is reasonable and adequately supported because the applicant based the projected payor mix on the facility's historical payor mix.

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.4, page 51, the applicant adequately describes the range of means by which patients will have access to the proposed services.

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.1, page 53, 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-1.

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 four dialysis stations to its existing facility for a total of 50 stations at BMA Raleigh upon completion of this project and Project ID #J-11510-18 (relocate four stations to FKC Holly Springs for a total of 46 at BMA Raleigh).

On page 365, the 2018 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."* BMA Raleigh is located in Wake County; thus, the service area for this facility consists of Wake County. Facilities may also serve residents of counties not included in their service area.

According to the July 2018 SDR, Wake County has the following existing dialysis facilities operated by Fresenius medical Care (FMC) and Davita.

Wake County Dialysis Facilities

Facility Name	Provider	Location	#of stations	Utilization
BMA of Fuquay-Varina Kidney Center	FMC	Fuquay-Varina	28	77.68%
BMA Raleigh Dialysis	FMC	Raleigh	50	91.50%
Cary Kidney Center	FMC	Cary	28	79.46%
FMC Apex	FMC	Apex	20	77.50%
FMC Central Raleigh	FMC	Raleigh	19	82.89%
FMC Eastern Wake	FMC	Rolesville	17	72.06%
FMC Millbrook	FMC	Raleigh	17	75.00%
FMC New Hope Dialysis	FMC	Raleigh	36	94.44%
FMC Northern Wake	FMC	Wake Forest	16	65.63%
Southwest Wake County Dialysis	FMC	Raleigh	30	97.50%
Wake Dialysis Clinic	FMC	Raleigh	50	94.50%
Wake Forest Dialysis Center	DaVita	Raleigh	22	94.32%
Zebulon Kidney Center	FMC	Zebulon	28	89.29%

Source: July 2018 SDR, Table B.

FMC related entities own and operate 12 of the 13 existing and proposed dialysis facilities in Wake County. The table shows that with the exception of one facility, the existing 13 Wake County facilities are all operating at above 72% capacity. In addition to the existing facilities listed above, the July 2018 SDR includes additional approved facilities consisting of relocated existing stations from facilities listed above.

In Section N.1, pages 54-55, the applicant discusses the expected effects of the proposed project on competition, including cost-effectiveness, quality and access, stating:

"BMA does not expect this proposal to have effect on the competitive climate in Wake County. BMA does not project to serve dialysis patients currently being served by another provider. The projected population for the BMA Raleigh facility begins with patients currently served by BMA and a growth of that patient population consistent with the Wake County five year average annual change rate of 4.3%% [sic] *as published within the July 2018 SDR.*

According to the July 2018 SDR there were 13 dialysis facilities operating within Wake County. There are two providers of dialysis services operating within Wake County: BMA and DaVita. These providers and dialysis facilities offer 388 dialysis stations to the more than 1300 ESRD patients of Wake County. BMA seeks the opportunity to continue providing dialysis care and treatment to the patients of the area who are already choosing dialysis at a BMA facility."

In addition, the applicant states that BMA facilities are compelled to operate efficiently as a result of fixed Medicare and Medicaid reimbursement rates. Moreover, the applicant states, on page 54, that its proposal will *"enhance the quality of the ESRD patients' lives by offering another convenient venue for dialysis care and treatment."*

The applicant adequately described 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 R of the application and any exhibits),
- quality services will be provided (see Sections B and O of the application and any exhibits), and
- access will be provided to underserved groups (see Sections B and L of the application and any exhibits).

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.

(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 A.11, page 4, the applicant states that Bio-Medical Applications of North Carolina, Inc. is a wholly owned subsidiary of Fresenius Medical Care Holdings, Inc. Exhibit A-4 includes a listing of 114 Fresenius related facilities in North Carolina. In Section O.3, page 59, the applicant states:

> *"As of June 30, 2018, Fresenius related facilities were providing dialysis care and treatment for more than 9,900 dialysis patients receiving care in a North Carolina dialysis facility."*

The applicant further states that during the 18 months immediately preceding the submittal of the application, there were no incidents related to quality of care (immediate jeopardy) in any of the FMC related facilities. After reviewing and considering information provided by the applicant and considering the quality of care provided at all Fresenius facilities, the applicant provided sufficient evidence that quality care has been provided in the past.

The Agency concludes the application is conforming to this criterion for the reasons stated above.

(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 proposal is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services in 10A NCAC 14C.2200. The specific findings are discussed below.

10 NCAC 14C .2203 PERFORMANCE STANDARDS

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

-NA- The applicant is not proposing to establish a new ESRD 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- Therefore, based on the methodology and assumptions above, the applicant projects that at the end of OY1, 191 patients will be dialyzing on 50 stations for a projected utilization rate of 3.82 patients per station per week (191 in-center patients / 50 stations = 3.82) which exceeds the minimum standard of 3.2 patients per station per week as required by 10A NCAC 14C.2203(b).

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

-C- The applicant provides all assumptions, including the methodology by which patient utilization is projected, in Section C.1, pages 13-14.