

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: February 27, 2019

Findings Date: March 4, 2019

Project Analyst: Jane Rhoe-Jones

Team Leader: Fatimah Wilson

Project ID #: J-11572-18

Facility: FMC New Hope Dialysis

FID #: 020868

County: Wake

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

Project: Add no more than eight dialysis stations for a total of no more than 36 stations upon completion of this project, Project ID #J-11271-16 (relocate six stations to FMC Rock Quarry), Project ID# J-11312-17 (add six stations), Project ID #J-11372-17 (relocate four stations to FKC Selma) and 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 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. (BMA and/or the applicant), d/b/a Fresenius Medical Care New Hope Dialysis (FMC New Hope) proposes to add eight dialysis stations to the existing facility for a total of 36 dialysis stations upon completion of this project, Project ID #J-11271-16 (relocate six stations to FMC Rock Quarry), Project ID# J-11312-17 (add six stations), Project ID #J-11372-17 (relocate four stations to FKC Selma) 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 in Wake County. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate reported for FMC New Hope in the July 2018 SDR is 3.7778 patients per station per week. This utilization rate was calculated based on 136 in-center dialysis patients and 36 certified dialysis stations as of December 31, 2017 (136 patients / 36 stations = 3.7778 patients per station per week). The facility need methodology requires a facility's utilization rate in the latest SDR 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 nine additional stations are needed for this facility, as illustrated in the following table.

OCTOBER 1 REVIEW-JULY 2018 SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/17		94.4%
Certified Stations		36
Pending Stations		6
Total Existing and Pending Stations		42
In-Center Patients as of 12/31/17 (July 2018 SDR) (SDR2)		136
In-Center Patients as of 6/30/17 (Jan 2018 SDR) (SDR1)		124
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	12
	Multiply the difference by 2 for the projected net in-center change	24
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/17	0.1935
(ii)	Divide the result of Step (i) by 12	0.0161
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/16 until 12/31/17)	0.1935
(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	162.3226
(v)	Divide the result of Step (iv) by 3.2 patients per station	50.7258
	and subtract the number of certified and pending stations to determine the number of stations needed	8.7258

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is nine stations. Rounding to the nearest whole number is allowed in Step (v) of the facility need methodology, as stated in the July 2018 SDR. 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 eight new stations and therefore, 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* on page 233 of the 2018 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.”

The applicant addresses *Policy GEN-3* as follows:

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section B.4(a and d), pages 8, and 10-11, respectively, Section K.1(g), page 46, Section N, page 56, Section O, pages 58-61, and Exhibits O-1 and O-2. 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 8-11, respectively, Section C.3, page 17, Section L, pages 50-54 and Section N, page 56. 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, Section C.3, page 17, Section K, pages 44-46 and Section N.1, page 56. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was 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 above stated reasons.

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

C

BMA proposes to add eight dialysis stations to FMC New Hope for a total of 36 dialysis stations upon completion of this project, Project ID #J-11271-16 (relocate six stations to FMC Rock Quarry), Project ID# J-11312-17 (add six stations), Project ID #J-11372-179 (relocate four stations to FKC Selma) and Project ID #J-11510-18 (relocate four stations to FKC Holly Springs).

FMC New Hope currently offers home hemodialysis (HHD) training and support services. The applicant does not currently offer peritoneal dialysis (PD) training and support services nor proposes to do so in this application.

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.*” 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 19 and Section C.1, page 13, the applicant provides historical and projected patient origin for in-center (IC) patients and HHD patients; in operating years 1 and 2 (OY1) and (OY2), as summarized in the following table:

FMC NEW HOPE DIALYSIS								
Current and Projected Patients by County of Residence								
County	Current As of June 30, 2018		OY1 CY2020		OY2 CY2021		County Patients as % of Total	
	IC Patients	HHD Patients	IC Patients	HHD Patients	IC Patients	HHD Patients	OY1 CY2020	OY2 CY2021
Wake	118	18	118.4	20.0	123.5	20.9	96.5%	96.7%
Granville	0	1	0	1	0	1	0.7%	0.7%
Johnston	2	2	0	2	0	2	1.4%	1.3%
Person	0	1	0	1	0	1	0.7%	0.7%
Vance	0	0	0	0	0	0	0	0
Wilson	1	0	1	0	1	0	0.7%	0.7%
Other States	1	0	0	0	0	0	0	0
Total	122	22	119	24	124	24	100.0%	100.0%

In Section C, pages 13-16, the applicant provides the assumptions and methodology used to project patient origin for both IC and HHD patients.

The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section B.2, page 6, the applicant states the application is filed pursuant to the facility need methodology in the 2018 SMFP utilizing data from the January 2018 and July 2018 SDR. The facility need methodology shows a need for nine dialysis stations and the proposed project is for eight dialysis stations.

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.”

In Section C, pages 13-14, the applicant states:

- The applicant uses the 4.3% Five Year Average Annual Change Rate (AACR) for Wake County patients as published in the July 2018 SDR.
- The applicant assumes that patients from other counties dialyzing with FMC New Hope are at the facility by choice and will continue to do so. The applicant does not project any increase in this patient population and they will be added in at appropriate points in time.
- The patient listed as residing in another state is assumed by the applicant to be a transient patient and the applicant does not project transient patients in its assumptions or methodology.

- In Project ID #J-11220-16, the applicant projected that four Wake County and one Johnston County dialysis patients would transfer their care from FMC New Hope to the FMC White Oak facility which was certified in August 2018. The applicant states in this project that it will allow time for those patients to complete their transfers and subtract them from the FMC New Hope patient census as of December 31, 2018.
- The applicant states that this project is planned to follow the development of the FMC Rock Quarry facility, Project ID #J-11271-16. The Rock Quarry project, per the applicant, has been delayed because of property and zoning issues. However, the issues were resolved in August 2018 and the facility has a projected certification date of December 2019. In that project, the applicant proposed to relocate six stations and transfer eight Wake County patients to the new Rock Quarry facility. The applicant will subtract those patients effective with the facility certification date.
- For FKC Selma, Project ID #J-11372-17, the applicant proposed to relocate four stations and transfer that one patient living in Johnston County to that facility. FKC Selma is also projected to be certified in December 2019; thus, that patient will be subtracted from the FMC New Hope census at that time.
- BMA did not propose to transfer any patients for Project ID #J-11510-18, the FKC Holly Springs proposal. However, four stations are proposed for relocation to that facility.
- Project years associated with this proposal are as follows:
 - Interim Year: January 1-December 31, 2018
 - Interim Year: January 1-December 31, 2019
 - OY1: January 1, 2020-December 31, 2020 (CY 2020)
 - OY2: January 1, 2021-December 31, 2021 (CY 2021)

The information is reasonable and adequately supported.

Projected Utilization

In Section C, page 15, the applicant provides the methodology used to project in-center patient utilization using the assumptions noted above, summarized as follows:

In-Center

Begin June 30, 2018 with the 118 Wake County patients	118
Project the Wake County in-center patients forward six months to December 31, 2017, using one-half of the Five-Year AACR for Wake County.	$118 \times 1.0215 = 120.5$
Subtract four Wake County patients projected to transfer their care to FMC White Oak. The Johnston County patient will not be carried forward.	$120.5 - 4 = 116.5$
Project this census forward 12 months to December 31, 2019; projected certification for this project.	$116.5 \times 1.043 = 121.5$
Subtract eight patients who are projected to transfer to FMC Rock Quarry. This is the beginning census for Operating Year 1. One Johnston County patient is expected to transfer care to FKC Selma; and is not carried forward.	$121.5 - 8 = 113.5$
Project the Wake County patient population forward one year to December 31, 2020 using the Five-Year AACR for Wake County.	$113.5 \times 1.043 = 118.4$
Add the one Wilson County patient projected to continue to dialyze at FMC New Hope. This is the ending census for Operating Year 1 .	$118.4 + 1 = \mathbf{119.4}$
Project the Wake County patient population forward one year to December 31, 2021 using the Five-Year AACR for Wake County.	$118.4 \times 1.034 = 123.5$
Add the one Wilson County patient projected to continue to dialyze at FMC New Hope. This is the ending census for Operating Year 2 .	$123.5 + 1 = \mathbf{124.5}$

The applicant states that patients for OY1 and OY2 are rounded down to the nearest whole number. Therefore, at the end of OY1 (CY 2020) and OY2 (CY 2021) the facility is projected to serve 119 and 124 in-center patients, respectively.

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

- OY1: 3.30 patients per station per week, or 82.6% [$119 \text{ patients} / 36 \text{ stations} = 3.30$; $3.30 / 4 = 0.8263$].
- OY2: 3.4 patients per station per week, or 86.1% [$124 \text{ patients} / 36 \text{ stations} = 3.44$; $3.44 / 4 = 0.8611$].

The projected utilization of 3.30 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).

Home Hemo Dialysis

The following table illustrates application of the methodology used to project HHD patient utilization in Section C, page 16:

Begin June 30, 2018 with the eighteen Wake County HHD patients	18
Project the Wake County HHD patients forward six months to December 31, 2018, using one-half of the Five Year AACR for Wake County	$18 \times 1.0218 = 18.4$
Project the Wake County HHD patients forward one year to December 31, 2019	$18.4 \times 1.043 = 19.2$
Project the Wake County HHD patients forward one year to December 31, 2020	$19.2 \times 1.043 = 20.0$
Add out of county patients. End of OY1	$20.0 + 4 = \mathbf{24}$
Project the Wake County patient population forward one year to December 31, 2021 using the Five-Year AACR for Wake County	$20.0 \times 1.043 = 20.9$
Add out of county patients. End of OY2	$20.9 + 4 = \mathbf{24.9}$

The assumptions for HHD projected utilization above, from page 15, is summarized below:

- The applicant begins with the 18 existing Wake County HHD patients.
- The applicant uses the Wake County 5 Year AACR to project growth in the HHD patient population.
- The applicant holds the existing patients from other NC counties who dialyze at the facility by choice and are proposed to remain at the facility constant.
- No HHD patients are projected to transfer to another facility

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

- The applicant begins with the existing Wake County IC and HHD patients as of the July 2018 SDR.
- The Wake County patients are projected to increase at a rate of 4.3% per year, consistent with the Five-Year AACR for Wake County as reported in Table D of the July 2018 SDR.
- The applicant holds the existing patients from other NC counties who dialyze at the facility by choice and are proposed to remain at the facility constant.
- The applicant subtracts the out of state patient and the patients who are proposed to relocate to other facilities upon completion of other projects.
- The resulting utilization rate at FMC New Hope Dialysis by the end of the first year of operation exceeds the minimum standard of 3.2 patients per station per week required by 10A NCAC 14C .2203.

Access

In Section C.3, page 17, the applicant states,

“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.”

In Section L.1, page 51, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown below in the table.

FMC NEW HOPE PROJECTED PAYOR MIX - OY2	
PAYOR CATEGORY	% OF TOTAL PATIENTS
Self-Pay/ Indigent/Charity	0.70%
Medicare	51.41%
Medicaid	7.04%
Commercial Insurance	13.38%
Medicare/Commercial	25.35%
Miscellaneous (incl. VA)	2.11%
Total	100.00%

On page 51, the applicant states the projected payor mix is based on the historical payor mix for a twelve-month period ending June 30, 2018. The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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 to reduce or eliminate a service, nor does the applicant propose to relocate 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

BMA proposes to add eight dialysis stations to FMC New Hope Dialysis for a total of 36 dialysis stations upon completion of this project, Project ID #J-11271-16 (relocate six stations to FMC Rock Quarry), Project ID# J-11312-17 (add six stations), Project ID #J-11372-17 (relocate four stations to FKC Selma) and Project ID #J-11510-18 (relocate four stations to FKC Holly Springs).

In Section E, page 23, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo – the applicant considered not applying for additional stations at New Hope Dialysis; however, the applicant states to do so is to ignore the reality of an increasing patient population in the service area and at the facility. Thus, there would be a lack of capacity and would necessitate denying patient admissions; given the projected utilization rate of 82.64% during OY1.
- Relocate Existing Stations from Another BMA Facility in Wake County – the applicant considered relocating stations from its other facilities in Wake County, but states that those facilities are already averaging a utilization rate of 84.22% or 3.37 patients per station. The applicant states, “... *is more prudent to develop additional stations to ensure sufficient capacity exists.*”

On page 23, the applicant states that its proposal is the least costly and most effective alternative because the proposed project will address both the issues of growth and access to the facility and not require any capital expenditures.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the above stated reasons. 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 and any clarifying responses. In the event that representations conflict, Bio-Medical Applications of North Carolina, Inc. shall materially comply with the last made representation.**
 2. **Pursuant to the facility need determination in the July 2018 SDR, Bio-Medical Applications of North Carolina, Inc. shall develop no more than eight additional dialysis stations for a total of no more than 36 certified stations at FMC New Hope Dialysis upon completion of this project, Project ID #J-11271-16 (relocate six stations to FMC Rock Quarry), Project ID# J-11312-17 (add six stations), Project ID #J-11372-17 (relocate four stations to FKC Selma) 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

BMA proposes to add eight dialysis stations to FMC New Hope Dialysis for a total of 36 dialysis stations upon completion of this project, Project ID #J-11271-16 (relocate six stations to FMC Rock Quarry), Project ID# J-11312-17 (add six stations), Project ID #J-11372-17 (relocate four stations to FKC Selma) and Project ID #J-11510-18 (relocate four stations to FKC Holly Springs).

Capital and Working Capital Costs

In Section F.1 and 2, pages 24-25, F.10 and F.11, page 28, the applicant states that the proposed project does not involve any capital expenditures or initial operating expenses, because the facility is currently operational.

Financial Feasibility

The applicant provides pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Form B, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown below in the table.

FMC NEW HOPE DIALYSIS		
	OY 1 (CY 2020)	OY 2 (CY 2021)
Total Treatments*	18,080	18,969
Total Gross Revenues (Charges)	\$82,739,036	\$85,694,144
Total Net Revenue	\$6,397,476	\$6,627,636
Average Net Revenue per Treatment	\$354	\$354
Total Operating Expenses (Costs)	\$5,413,008	\$5,572,677
Average Operating Expense per Treatment	\$299	\$294
Net Income	\$984,468	\$1,054,959

Source: Application Form C assumptions. *Treatments adjusted for missed treatments.

In Section C in the applicant’s assumptions, OY1 is stated as 2020 and OY2 as 2021; although in some of the pro forma financial statements the applicant states the first two operating years of the proposed project as OY1 is 2019 and OY2 is 2020. In the proposed timetable in Section R, page 63, the applicant is using 2019 as OY1, when services will be offered. In clarifying information requested and received by the by the Agency on February 5, 2019, the applicant states CY2020 as OY1 and CY2021 as OY2.

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
- Exhibits to the application
- Clarifying information requested and received by the Agency on February 5, 2019.

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

- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal.
- 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

BMA proposes to add eight dialysis stations to FMC New Hope Dialysis for a total of 36 dialysis stations upon completion of this project, Project ID #J-11271-16 (relocate six stations

to FMC Rock Quarry), Project ID# J-11312-17 (add six stations), Project ID #J-11372-17 (relocate four stations to FKC Selma) and Project ID #J-11510-18 (relocate four stations to FKC Holly Springs).

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.*” Thus, the service area for this facility consists of Wake County. Facilities may also serve residents of counties not included in their service area.

Currently, there are 18 existing and approved dialysis facilities in Wake County, 16 of which are owned by BMA. DaVita operates one dialysis facility in Wake County, and has one approved but not yet operational, as shown in the following table:

WAKE COUNTY DIALYSIS FACILITIES				
FACILITY	OWNER	LOCATION	# CERTIFIED STATIONS AS OF 12/31/17	UTILIZATION AS OF 12/31/17
FMC New Hope Dialysis	FMC	Raleigh	36	94.44%
BMA of Fuquay Varina Kidney Center	FMC	Fuquay Varina	28	77.68%
BMA of 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	14	72.06%
FMC Millbrook	FMC	Raleigh	17	75.00%
FMC Northern Wake	FMC	Wake Forest	16	65.63%
Southwest Wake County Dialysis	FMC	Raleigh	30	97.50%
Wake Dialysis Center	FMC	Raleigh	50	94.50%
Zebulon Kidney Center	FMC	Zebulon	30	83.33%
FMC Morrisville	FMC	Morrisville	10*	NA
FMC White Oak	FMC	Garner	12*	NA
FMC Rock Quarry	FMC	Raleigh	10*	NA
FKC Holly Springs	FMC	Holly Springs	10*	NA
Wake Forest Dialysis Center	DaVita	Raleigh	22	94.32%
Oak City Dialysis	DaVita	Raleigh	10*	NA

Source: Table B, July 2018 SDR. *Certificate of need approved, not developed as of June 1, 2018; the SDR cut-off date. The FMC Morrisville and FMC White Oak facilities were recently certified.

As shown in the table above, four of the 12 operational dialysis facilities owned by BMA were being utilized at 90% or higher; seven were being utilized at greater than 70.0% and one facility was being utilized at 65.63%.

In Section G.2, page 34, 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:

“... An evaluation of all BMA facilities in Wake County demonstrates that on the whole, BMA facilities in Wake County are operating above 80% utilization.

BMA also evaluated access by geography. Wake County is the second most populated county in NC. ... Thus, access to care should consider more than just distance to the facility, but also how much time is involved in getting to dialysis. BMA seeks to ensure adequate and convenient access to care for the ESRD patients of Wake County.” [On page 34, the applicant provides a map depicting dialysis facilities in Wake County] “As the map demonstrates, the existing facilities in Wake County are widely dispersed across the county. ... Addition of eight stations to FMC New Hope will not duplicate services. It will only ensure access to care for the patients choosing to dialyze at the facility.”

In Section E.1, page 23, the applicant states:

“Based upon such high utilization overall, BMA does not believe it prudent to relocate stations. Rather it is more prudent to develop additional stations to ensure sufficient capacity exists.”

The applicant is proposing to add eight dialysis stations based on facility need, and demonstrates that the facility was serving 136 patients weekly on 36 dialysis stations, which is 3.7778 patients per station, or 94.44% of capacity as of June 30, 2018 [$136 / 36 = 3.7778$; $3.7778 / 4 = 0.9444$]. The applicant does not propose the development of a new dialysis facility; rather, this application seeks to address the needs of this facility by adding needed stations.

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 additional eight 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
- The applicant 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
- Information which was 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 above stated reasons.

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

C

In Section H.1, page 35, the applicant provides the current and projected staffing table for the facility and shows in the following table that FMC New Hope Dialysis is not projected to add any full time equivalent (FTE) positions as a result of this proposal.

FMC NEW HOPE CURRENT AND PROPOSED FTE STAFFING			
POSITION	CURRENT POSITIONS	ADJUSTMENTS	PROPOSED POSITIONS
Registered Nurse	8.00	0	8.00
Home Training Nurse	2.00	0	2.00
LPN	1.00	0	1.00
Patient Care Technician	19.00	0	19.00
Dietician	1.00	0	1.00
Social Worker	1.00	0	1.00
Clinical Manager	1.00	0	1.00
Administrator	0.15	0	0.15
In-Service	0.25	0	0.25
Clerical	1.00	0	1.00
Chief Technician	0.15	0	0.15
Equipment Technician	1.00	0	1.00
Total	35.55	0	35.55

The applicant provides projected direct care staff in OY2 in Section H.7, page 38.

Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, which is found in Section R. In Sections H.3 and H.4, page 36, the applicant describes the methods used to recruit personnel or fill new positions and its existing training and continuing education programs. In Exhibits H-1 and H-2, the applicant provides supporting documentation. In Section I.3, page 41, the applicant identifies the current medical director. In Exhibit I-5, the applicant provides a letter from the medical director indicating an interest in continuing to serve in that capacity following the addition of eight stations.

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

Conclusion

The Agency reviewed the:

- Application
- 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.1, page 39, the applicant identifies the ancillary and support services necessary for the proposed services, as shown below in the table.

FMC NEW HOPE DIALYSIS ANCILLARY AND SUPPORT SERVICES	
Services	Provider
In-center dialysis/maintenance	BMA
Self-care training (in-center)	BMA
Home training Hemodialysis Peritoneal Dialysis Accessible follow-up program	BMA BMA (Wake Dialysis Clinic) On site (HHD) & Wake Dialysis Clinic (PD)
Psychological counseling	Wake County Mental Health
Isolation – hepatitis	BMA
Nutritional counseling	BMA
Social Work services	BMA
Acute dialysis in an acute care setting	Wake Medical Center
Emergency care	BMA & Wake Medical Center
Blood bank services	Wake Medical Center or UNC Rex
Diagnostic and evaluation services	Wake Medical Center, Raleigh Radiology, or patient choice
X-ray services	Wake Medical Center, Raleigh Radiology, or patient choice
Laboratory services	Spectra Labs
Pediatric nephrology	UNC
Vascular surgery	Carolina Vascular, Wake Surgical, North Raleigh Surgical or Carolina Surgery
Transplantation services	Duke
Vocational rehabilitation & counseling	Vocational Rehabilitation of Wake County
Transportation	Wake County Transportation Services, TRACS, ART (Go Raleigh)

The applicant provides supporting documentation in Exhibit I.

In Section I, pages 40-42, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibits I-3 and I-4.

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

Conclusion

The Agency reviewed the:

- Application
- 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 to construct any new space nor renovate any existing space, since the facility currently has space for the additional stations proposed in this application. 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 54, the applicant provides the historical payor mix during CY2017 for the proposed services, as shown below in the table.

FMC NEW HOPE DIALYSIS CY2017 Payor Mix	
PAYOR CATEGORY	SERVICES AS PERCENT OF TOTAL
Self-Pay / Indigent / Charity	1.64%
Medicare	49.94%
Medicaid	9.06%
Commercial	12.21%
Medicare Commercial	24.80%
Miscellaneous (Includes VA)	2.36%
Total	100.00%

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

Percent of Population						
County	% 65+	% Female	% Racial 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 25-26¹) 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.

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was 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;

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.3(e), pages 52-53, the applicant states:

“BMA 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 Section L.6, page 53, the applicant states that during the last five years no patient civil rights access complaints have been filed against any BMA North Carolina facilities.

The Agency reviewed the:

- Application
- 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 51, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown below in the table.

FMC NEW HOPE DIALYSIS PROJECTED PAYOR MIX – PY2	
PAYOR CATEGORY	SERVICES AS PERCENT OF TOTAL
Self-Pay / Indigent / Charity	0.70%
Medicare	51.41%
Medicaid	7.04%
Commercial	13.38%
Medicare Commercial	25.35%
Miscellaneous (Includes VA)	2.11%
Total	100.00%

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 0.70% of total services will be provided to self-pay/indigent/charity patients, 51.41% to Medicare patients and 7.04% to Medicaid patients.

On page 51, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical payor mix for FMC New Hope Dialysis from July 1, 2017 to June 30, 2018.

The Agency reviewed the:

- Application
- 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 53, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- 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 55, 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
- 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

BMA proposes to add eight dialysis stations to FMC New Hope Dialysis for a total of 36 dialysis stations upon completion of this project, Project ID #J-11271-16 (relocate six stations to FMC Rock Quarry), Project ID# J-11312-17 (add six stations), Project ID #J-11372-17 (relocate four stations to FKC Selma) and Project ID #J-11510-18 (relocate four stations to FKC Holly Springs).

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.*” Thus, the service area for this facility consists of Wake County. Facilities may also serve residents of counties not included in their service area.

Currently, there are 18 existing and approved dialysis facilities in Wake County, 16 of which are owned by BMA. DaVita operates one dialysis facility in Wake County, and has one approved but not yet operational, as shown in the following table:

WAKE COUNTY DIALYSIS FACILITIES				
FACILITY	OWNER	LOCATION	# CERTIFIED STATIONS AS OF 12/31/17	UTILIZATION AS OF 12/31/17
FMC New Hope Dialysis	FMC	Raleigh	36	94.44%
BMA of Fuquay Varina Kidney Center	FMC	Fuquay Varina	28	77.68%
BMA of 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	14	72.06%
FMC Millbrook	FMC	Raleigh	17	75.00%
FMC Northern Wake	FMC	Wake Forest	16	65.63%
Southwest Wake County Dialysis	FMC	Raleigh	30	97.50%
Wake Dialysis Center	FMC	Raleigh	50	94.50%
Zebulon Kidney Center	FMC	Zebulon	30	83.33%
FMC Morrisville	FMC	Morrisville	10*	NA
FMC White Oak	FMC	Garner	12*	NA
FMC Rock Quarry	FMC	Raleigh	10*	NA
FKC Holly Springs	FMC	Holly Springs	10*	NA
Wake Forest Dialysis Center	DaVita	Raleigh	22	94.32%
Oak City Dialysis	DaVita	Raleigh	10*	NA

Source: Table B, July 2018 SDR. *Certificate of need approved, not developed as of June 1, 2018; the SDR cut-off date. The FMC Morrisville and FMC White Oak facilities were recently certified.

As shown in the table above, four of the 12 operational dialysis facilities owned by BMA were being utilized at 90% or higher; seven were being utilized at greater than 70.0% and one facility was being utilized at 65.63%.

In Section N, page 56, 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. On page 56, the applicant states:

“BMA does not expect this proposal to have effect on the competitive climate in Wake County. ... The projected patient population for the facility begins with patients currently served by BMA [at FMC New Hope Dialysis], and a growth of that patient population consistent with the Wake County five year average annual change rate of 4.3% as published within the July 2018 SDR.”

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 F and R of the application and any exhibits)
- Quality services will be provided (see Section O of the application and any exhibits)

- Access will be provided to underserved groups (see Section L of the application and any exhibits)

Conclusion

The Agency reviewed the:

- Application
- 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 O.3, page 61, the applicant states there are more than 100 Fresenius related dialysis facilities and more than 9,900 dialysis patients located in North Carolina. The applicant states that during the 18 months immediately preceding the submittal of the application, there were no incidents related to quality of care that resulted in an Immediate Jeopardy in any of these facilities. See Exhibit O-2 which contains a letter from CMS stating that New Hope Dialysis meets the Conditions for Coverage for ESRD 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. 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

SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES

10A 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- The applicant is not proposing to establish a new End Stage Renal Disease 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 C.1, pages 13 and 15, the applicant projects to serve 119 in-center patients by the end of OY1 (CY2020) for a utilization rate of 82.63% or 3.30 patients per station per week (119 patients / 36 stations = 3.30; $3.30 / 4 = 0.8263$ or 82.63%). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

-C- In Section C, pages 13-15, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.