

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: March 29, 2019

Findings Date: March 29, 2019

Project Analyst: Mike McKillip

Team Leader: Gloria Hale

Project ID #: F-11633-18

Facility: FMC Regal Oaks

FID #: 150024

County: Mecklenburg

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

Project: Relocate no more than three dialysis stations from FMC Charlotte to FMC Regal Oaks for a total of no more than 15 dialysis stations at FMC Regal Oaks upon project completion

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) d/b/a FMC Regal Oaks proposes to relocate no more than three dialysis stations from FMC Charlotte to FMC Regal Oaks for a total of no more than 15 dialysis stations at FMC Regal Oaks upon project completion.

Need Determination

The applicant is proposing to relocate three dialysis stations from FMC Charlotte in Mecklenburg County to FMC Regal Oaks also in Mecklenburg County, therefore there are no need methodologies in the 2018 State Medical Facilities Plan (2018 SMFP) applicable to this review.

Policies

There is one policy in the 2018 SMFP which is applicable to this review. *Policy ESRD-2: Relocation of Dialysis Stations*, on page 27. Policy ESRD-2 states:

“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties. Certificate of need applicants proposing to relocate dialysis stations to a contiguous county shall:

- 1. Demonstrate that the facility losing dialysis stations or moving to a contiguous county is currently serving residents of that contiguous county; and*
- 2. Demonstrate that the proposal shall not result in a deficit, or increase an existing deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*
- 3. Demonstrate that the proposal shall not result in a surplus, or increase an existing surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.”*

FMC Regal Oaks and FMC Charlotte are both located in Mecklenburg County. Therefore the proposed project is consistent with Policy ESRD-2.

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 because the application is consistent with Policy ESRD-2.

- (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 relocate three dialysis stations from FMC Charlotte to FMC Regal Oaks for a total of 15 dialysis stations at FMC Regal Oaks upon project completion. Both facilities are located in Mecklenburg County.

The following tables, summarized from Section A.9, page 4 of the application, show the FMC Regal Oaks facility, and the FMC Charlotte facility from which the applicant plans to relocate three stations.

FMC Regal Oaks		
Stations	Description	Project ID #
12	Total existing certified stations as of the July 2018 SDR	
+3	Stations to be added as part of this project	F-11633-18
15	Total stations upon completion of above project	
FMC Charlotte		
Stations	Description	Project ID #
44	Total existing certified stations as of the July 2018 SDR	
0	Stations to be added but not yet certified	
-3	Stations to be deleted as part of this project	F-11633-18
+1	Stations to be added as part of another project	F-11582-18
0	Stations to be deleted as part of this project	
42	Total stations upon completion of above projects	

As shown in the table above, upon project completion, FMC Regal Oaks will be certified for 15 dialysis stations, and FMC Charlotte will be certified for 42 dialysis stations.

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

In Section C.1, page 13, and Section C.8, page 17, respectively, the applicant provides the historical and projected patient origin for FMC Regal Oaks in-center patients, as illustrated in the table below.

FMC Regal Oaks Patient Origin

County of Residence	Historical (11/1/2018)		OY1 CY2020	OY2 CY2021	Projected Patients as a Percent of Total	
	In-Center Patients	% of Total	In-Center Patients	In-Center Patients	OY1 CY2020	OY2 CY2021
Mecklenburg	41	100%	50.4	55.5	100%	100%
TOTAL	41	100%	50	55	100%	100%

On page 13 of the application, the applicant states FMC Regal Oaks is not certified to provide home dialysis therapies. In Section C.1, pages 13-15, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 13-15, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services.

On pages 13-15, the applicant states:

- The applicant begins the projections for FMC Regal Oaks by using the ending in-center patient census of 41 patients as of October 31, 2018, all of whom were residents of Mecklenburg County.
- The applicant uses a ten percent annual growth rate to project the FMC Regal Oaks patient census forward. The applicant states it does not believe that the Mecklenburg County Five Year Average Annual Change Rate (AACR) of 3.9 percent is appropriate because of the historical growth at the facility. The applicant states the facility’s patient census has increased by 20 patients in the 10 months since December 31, 2017 (January 1, 2018 through October 31, 2018), which is equivalent to an average annual growth rate of 114 percent from December 31, 2017 to October 31, 2018.
- Operating Year 1 (OY1) = January 1 through December 31, 2020 (CY2020).
 Operating Year 2 (OY2) = January 1 through December 31, 2021 (CY2021).

Projected Utilization

In Section C, page 14, the applicant provided the methodology used to project in-center utilization, as illustrated in the following table,

The applicant begins with the Mecklenburg County in-center patients as of October 31, 2018.	41
The applicant projects the Mecklenburg County patients forward two months to December 31, 2018 using one-sixth of the applicant's assumed growth rate (10%), which is 0.0167%.	$41 \times 1.0167 = 41.7$
The applicant projects the Mecklenburg County in-center patients forward one year to December 31, 2019 using the applicant's assumed growth rate of 10%.	$41.7 \times 1.10 = 45.9$
The applicant projects the Mecklenburg County in-center patients forward one year to December 31, 2020 using the applicant's assumed growth rate of 10%. This is the projected ending census for Operating Year 1.	$45.9 \times 1.10 = 50.4$
The applicant projects the Mecklenburg County in-center patients forward one year to December 31, 2021 using the applicant's assumed growth rate of 10%. This is the projected ending census for Operating Year 2.	$50.4 \times 1.10 = 55.5$

The applicant projects to serve 50 in-center patients in OY1 and 55 in-center patients in OY2. Thus, the applicant projects that FMC Regal Oaks will have a utilization rate of 83.33% or 3.33 patients per station per week (50 patients / 15 stations = 3.33 / 4 = 0.8333 or 83.33%) in OY1. The projected utilization of 3.33 patients per station per week at the end of OY1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

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

- The applicant begins with the existing patients as of October 31, 2018.
- The applicant projects the Mecklenburg County patient census at FMC Regal Oaks will increase by 10 percent per year, which is higher than the Mecklenburg County Five Year AACR of 3.9 percent, as reported in the July 2018 SDR, but less than the facility's actual historical average annual change rate from December 31, 2017 to October 31, 2018.
- The utilization rate by the end of OY1 is above the minimum standard of 3.2 patients per station per week.

Home Hemodialysis and Peritoneal Dialysis

FMC Regal Oaks does not offer home hemodialysis or peritoneal dialysis training nor does the applicant propose to add those services. In Section I, page 41, the applicant states those patients that require home hemodialysis or peritoneal dialysis will be referred to FMC Charlotte. In Exhibit I.1, the applicant provides a copy of the home training agreement.

Access

In Section C.3, pages 15-16, the applicant states that each of BMA’s 114 facilities in 48 North Carolina counties has a patient population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, or other traditionally underserved persons. Services are provided to all patients, regardless of their ability to pay. In Section L.1, page 53, the applicant provides the projected payor mix during the second full fiscal year of operation following completion of the project (CY2021) for FMC Regal Oaks, as illustrated below.

Payor Source	Percent of Total Revenue
Self Pay/ Indigent/ Charity	1.47%
Medicare	65.70%
Medicaid	5.25%
Commercial Insurance	11.37%
Medicare / Commercial	11.32%
Misc. (VA)	4.90%
Total	100.00%

As illustrated in the table above, the applicant projects that 82.3% of all FMC Regal Oaks patients will be Medicare or Medicaid recipients in CY2021. On page 53, the applicant states its projected payor mix in Operating Year 2 is based on the facility’s *“performance for the 12 months ended September 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.

C

The applicant proposes to relocate three dialysis stations from FMC Charlotte to FMC Regal Oaks for a total of 15 dialysis stations at FMC Regal Oaks upon project completion. Both facilities are located in Mecklenburg County.

In Section D, pages 21-23, the applicant explains why it believes the needs of the population presently utilizing the services to be reduced, eliminated or relocated will be adequately met following completion of the project.

The applicant assumes that the number of in-center patients at FMC Charlotte who live in Mecklenburg County will increase at 3.9 percent per year based on the Five Year AACR for Mecklenburg County, as reported in Table D of the July 2018 SDR. The applicant serves four patients from others counties and assumes those patients will continue to dialyze at FMC Charlotte, but does not project any increase in the number of out-of-county patients to be served at FMC Charlotte. In Section D.1, page 22, the applicant calculates the in-center patient census for FMC Charlotte starting June 30, 2018 through December 31, 2019, summarized as follows:

The applicant begins with the Mecklenburg County in-center patients as of June 30, 2018.	156
The applicant projects the Mecklenburg County patients forward six months to December 31, 2018 using one-half of the Mecklenburg County AACR of 3.9 percent, or 1.95 percent.	$156 \times 1.0195 = 159.0$
The applicant projects the Mecklenburg County in-center patients forward one year to December 31, 2019 using the applicant's assumed growth rate of 3.9 percent.	$159.0 \times 1.039 = 165.2$
The applicant adds four patients from other counties. This is projected patient census at FMC Charlotte on the completion date of the proposed project.	$165.2 + 4 = 169.2$

In Section D, page 22, the applicant states that BMA rounds the patient population of 169.2 up to 170 in-center patients for a utilization of 101% or 4.05 patients per station, per week. This is based on 170 in-center patients dialyzing on 42 certified dialysis stations ($170 / 42 = 4.05$; $4.05 / 4 = 1.01$ or 101%). On page 22, the applicant states,

“BMA recognizes that utilization rates exceeding 100% necessarily result in a third or evening dialysis shift. FMC Charlotte already operates a third shift for patient choice and convenience. At the time this application is prepared, there are 23 patients dialyzing on the third shift. Thus in a practical sense, utilization would be a function of 147 patients dialyzing on 42 stations. Utilization would be calculated to be 3.5 patients per station, or 87.50% utilization.

As an additional consideration, BMA notes that in-center census at FMC Charlotte was 162 patients as of June 30, 2018. The facility was certified for 44 stations. Thus, utilization was 92.05%. The facility therefore will qualify to apply for additional stations by application of the Facility Need Methodology, arising from the January 2019 SDR. ... BMA expects that no patients will be denied service by the proposed relocation (and decertification) of stations at FMC Charlotte.”

Home Hemodialysis and Peritoneal Dialysis

Home hemodialysis and peritoneal dialysis are currently offered at FMC Charlotte, but the applicant states the proposed relocation of dialysis stations will have no impact on the home dialysis patients.

Projected utilization is reasonable and adequately supported based on the following reasons:

- The applicant begins its utilization projection with the existing Mecklenburg County patient census currently served at FMC Charlotte.
- The applicant projects the Mecklenburg County in-center patient census at FMC Charlotte will increase at the Mecklenburg County Five Year AACR of 3.9 percent, as reported in the July 2018 SDR.
- The applicant projects the number of patients from other counties that are dialyzing at FMC Charlotte will remain constant.

On page 23, the applicant states, *“This relocation of stations will not have any effect upon the ability of low income persons, racial and ethnic minorities, women, handicapped persons, the elderly and other underserved groups to obtain needed health care.”*

The applicant states that the proposed relocation of stations will not have an effect upon access to care for any patient.

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 applicant adequately demonstrates that:

- The needs of the population currently using the services to be reduced, eliminated or relocated will be adequately met following project completion.
- The project will not adversely impact the ability of underserved groups to access these services following project completion.

- (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 relocate three dialysis stations from FMC Charlotte to FMC Regal Oaks for a total of 15 dialysis stations at FMC Regal Oaks upon project completion. Both facilities are located in Mecklenburg County.

In Section E.1, pages 24-25, 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 states that maintaining the status quo is not an effective alternative because the utilization at FMC Regal Oaks continues to grow. Failure to add additional stations could result in forcing patients to a third shift, or forcing patients to travel further for dialysis care and services. Therefore, this alternative was rejected.
- Relocate stations from another BMA facility in Mecklenburg County - The applicant states all of the existing Mecklenburg County facilities are well-utilized, operating at or above 80 percent utilization levels. Therefore, this alternative was rejected.
- Relocate more than three stations from FMC Charlotte - The applicant states it considered relocating more than three stations from FMC Charlotte but determined it was not a reasonable alternative considering the utilization at FMC Charlotte. Therefore, the applicant rejected this alternative.

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

- As of November 1, 2018, FMC Regal Oaks operated above 80% capacity.

- Maintaining the status quo does not address the need for additional stations at the facility and could result in a third shift or patients having to travel further for services.
- The other BMA facilities located in Mecklenburg County are currently operating above 80% capacity.

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 reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Regal Oaks shall materially comply with all representations made in the certificate of need application.**
 - 2. Pursuant to Policy ESRD-2, Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Regal Oaks shall relocate no more than three dialysis stations from FMC Charlotte to FMC Regal Oaks for a total of no more than 15 dialysis stations at FMC Regal Oaks upon project completion.**
 - 3. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Regal Oaks shall install plumbing and electrical wiring through the walls for no more than three additional dialysis stations which shall include any isolation stations.**
 - 4. Upon completion of this project, Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify three dialysis stations at FMC Charlotte for a total of no more than 42 dialysis stations at FMC Charlotte upon completion of this project and Project I.D. # F-11582-18.**
 - 5. Bio Medical Applications of North Carolina, Inc. d/b/a FMC Regal Oaks 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 relocate three dialysis stations from FMC Charlotte to FMC Regal Oaks for a total of 15 dialysis stations at FMC Regal Oaks upon project completion.

Capital and Working Capital Costs

In Section F, page 27, the applicant projects the total capital cost of the project, as shown in the table below.

Miscellaneous Costs:	
Water Treatment Equipment	\$2,250
Other Equipment/Furniture	\$9,000
Total	\$11,250

In Section F, page 31, the applicant states that there will be no start-up costs or initial operating expenses associated with the proposed project because FMC Regal Oaks is an existing facility.

Availability of Funds

In Section F, page 28, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing

Type	Bio-Medical Applications of North Carolina, Inc.	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$11,250	\$11,250
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$11,250	\$11,250

* OE = Owner's Equity

Exhibit F.1 contains a letter dated November 15, 2018, from the Senior Vice President and Treasurer of Fresenius Medical Care Holdings, Inc., expressing the applicant's intention to finance the projected capital cost of the project with cash reserves of the applicant.

Exhibit F.2 contains the Balance Sheet for Fresenius Medical Care Holdings, Inc. and Subsidiaries which indicates that it had \$569.8 million in cash and cash equivalents as of December 31, 2017, \$19.8 billion in total assets and \$10.5 billion in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of funds.

Financial Feasibility

In Section R, the applicant provided pro forma financial statements for the first two full fiscal years of operation following completion of the project. In the pro forma financial statement (Form B), the applicant projects 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 Treatments	7,113	7,706
Total Gross Revenues (Charges)	\$28,366,644	\$30,731,528
Total Net Revenue	\$2,106,442	\$2,282,052
Average Net Revenue per Treatment	\$296.14	\$296.14
Total Operating Expenses (Costs)	\$1,801,338	\$1,807,629
Average Operating Expense per Treatment	\$253.25	\$234.57
Net Income	\$305,104	\$474,423

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
- 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 availability of sufficient funds for the capital needs of the proposal.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

The applicant proposes to relocate three dialysis stations from FMC Charlotte to FMC Regal Oaks for a total of 15 dialysis stations at FMC Regal Oaks upon project completion.

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

According to Table B of the July 2018 SDR, there are 23 facilities which provide dialysis in Mecklenburg County, 17 of which are operational. Information on all 23 of these dialysis facilities, from Table B of the July 2018 SDR, is provided below:

Mecklenburg County Dialysis Facilities Certified Stations and Utilization as of December 31, 2017				
Dialysis Facility	Owner	Location	# of Certified Stations	Utilization
BMA Beatties Ford	BMA	Charlotte	32	89.84%
BMA Nations Ford	BMA	Charlotte	28	91.96%
BMA of East Charlotte	BMA	Charlotte	26	88.46%
BMA of North Charlotte	BMA	Charlotte	40	98.75%
BMA West Charlotte	BMA	Charlotte	29	87.93%
FKC Mallard Creek*	BMA	Charlotte	0	0.00%
FMC Regal Oaks	BMA	Charlotte	12	43.75%
FKC Southeast Charlotte*	BMA	Charlotte	0	0.00%
FMC Aldersgate*	BMA	Charlotte	0	0.00%
FMC Charlotte	BMA	Charlotte	44	89.20%
FMC Matthews	BMA	Matthews	21	115.48%
FMC Southwest Charlotte	BMA	Charlotte	13	84.62%
Brookshire Dialysis*	DaVita	Charlotte	0	0.00%
Carolinas Medical Center	CMC	Charlotte	9	25.00%
Charlotte Dialysis	DaVita	Charlotte	36	86.11%
Charlotte East Dialysis	DaVita	Charlotte	34	90.44%
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	69.79%
DSI Glenwater Dialysis	DSI	Charlotte	42	75.00%
Huntersville Dialysis	DaVita	Huntersville	14	83.93%
Mint Hill Dialysis	DaVita	Mint Hill	16	84.38%
North Charlotte Dialysis Center	DaVita	Charlotte	37	68.24%
South Charlotte Dialysis**	DaVita	Charlotte	23	83.70%
South Charlotte Dialysis*	DaVita	Charlotte	0	0.00%
Sugar Creek Dialysis*	DaVita	Charlotte	0	0.00%

Source: July 2018 SDR, Table B.

* Facility under development.

**Per Project I.D. #F-11323-17, this facility is being relocated to a new location.

In Section G, pages 36-37, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Mecklenburg County. The applicant states:

“The existing and planned facilities are geographically dispersed across Mecklenburg County. BMA proposes to relocate three stations to FMC Regal Oaks. This will not duplicate existing services.”

The applicant proposes to relocate three dialysis stations from FMC Charlotte to FMC Regal Oaks for a total of 15 dialysis stations at FMC Regal Oaks upon project completion. Both facilities are located in Mecklenburg County. Therefore, the applicant proposes no change in the total inventory of dialysis stations in Mecklenburg County.

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 adequately demonstrates that the proposed relocation of three dialysis stations to FMC Regal Oaks is needed.
- The proposal does not increase the number of dialysis stations in Mecklenburg 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 reasons stated above.

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

C

In Section H, page 38, the applicant provides the current and projected staffing for the proposed services. The applicant does not propose additional FTE positions, as illustrated in the following table.

POSITION	CURRENT # FTES	PROJECTED # FTES YEAR 2 (CY2021)
Registered Nurse	2.00	2.00
Patient Care Technician	5.00	5.00
Dietician	0.50	0.50
Social Worker	0.50	0.50
Clinical Manager	1.00	1.00
Admin. (Dir. Ops)	0.15	0.15
In-Service	0.15	0.15
Clerical	0.50	0.50
Chief Tech	0.10	0.10
Equipment Tech	0.40	0.40
Total	10.30	10.30

The assumptions and methodology used to project staffing are provided in Section H and Section R. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, pages 66-67, which is found in Section R. In Section H, pages 38-39, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Exhibit I.5, the applicant provides a letter from the medical director indicating his interest in continuing to serve as the medical director of FMC Regal Oaks. In Exhibits H.1 and H.2, the applicant provides supporting documentation.

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, page 41, the applicant provides a list of the necessary ancillary and support services, as illustrated below.

FMC Regal Oaks Ancillary and Support Services	
Services	Provider
In-center dialysis/maintenance	FMC Regal Oaks (on site)
Self-care training (in-center)	FMC Charlotte
Home training HH PD Accessible follow-up program	FMC Charlotte
Psychological counseling	Atrium/Novant Mental Health
Isolation – hepatitis	FMC Regal Oaks (on site)
Nutritional counseling	FMC Regal Oaks (on site)
Social Work services	FMC Regal Oaks (on site)
Acute dialysis in an acute care setting	Carolinas Medical Center
Emergency care	Carolinas Medical Center
Blood bank services	Carolinas Medical Center
Diagnostic and evaluation services	Carolinas Medical Center
X-ray services	Carolinas Medical Center
Laboratory services	Spectra
Pediatric nephrology	Carolinas Medical Center
Vascular surgery	Surgical Specialists of Charlotte Metrolina Vascular Specialists
Transplantation services	Carolinas Medical Center
Vocational rehabilitation & counseling	Charlotte Vocational Rehabilitation Center
Transportation	Charlotte Area Transit (CATS), City Cab; Salvation Army, Wheels-U-Trust; Prestige Transportation, Mecklenburg Transit System

The applicant provides supporting documentation in Exhibits I.1-5. Exhibits I-1 through I-4, respectively, contain copies of an agreement for home training with FMC Charlotte, Spectra for laboratory services, and Carolinas Medical Center (Atrium) for transfer agreement and transplant services.

In Section I, pages 41-43, the applicant describes its existing and proposed relationships with other local healthcare and social service providers and provides supporting documentation in Exhibit I.5.

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 new space nor renovate the existing space. 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 56, the applicant provides the historical payor mix from January 1, 2017 to December 31, 2017 for the existing services, as shown in the table below.

Payor Source	Percent of Total Treatments
Self Pay/ Indigent/ Charity	1.49%
Medicare	67.88%
Medicaid	2.53%
Commercial Insurance	14.47%
Medicare / Commercial	13.63%
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
Mecklenburg	11%	52%	52%	14%	6%	13%
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.

Conclusion

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

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;

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 54, 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 Act.”

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 53, 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 in the table below.

**Projected Payor Mix
Year 2 (CY2021)**

Payor Source	Percent of Total Treatments
Self Pay/ Indigent/ Charity	1.47%
Medicare	65.70%
Medicaid	5.25%
Commercial Insurance	11.37%
Medicare / Commercial	11.32%
Misc. (VA)	4.90%
Total	100.00%

The applicant projects 77 percent of total treatments will be provided to Medicare patients (includes Medicare and Medicare/Commercial), 1.47 percent to self pay/indigent/charity care patients, and 5.25 percent to Medicaid patients.

On page 53, 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 utilization at FMC Regal Oaks for year ended September 30, 2018.

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.

- (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 55, 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 57, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.1.

Conclusion

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

The applicant proposes to relocate three dialysis stations from FMC Charlotte to FMC Regal Oaks for a total of 15 dialysis stations at FMC Regal Oaks upon project completion.

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

According to Table B of the July 2018 SDR, there are 23 facilities which provide dialysis in Mecklenburg County, 17 of which are operational. Information on all 23 of these dialysis facilities, from Table B of the July 2018 SDR, is provided below:

Mecklenburg County Dialysis Facilities Certified Stations and Utilization as of December 31, 2017				
Dialysis Facility	Owner	Location	# of Certified Stations	Utilization
BMA Beatties Ford	BMA	Charlotte	32	89.84%
BMA Nations Ford	BMA	Charlotte	28	91.96%
BMA of East Charlotte	BMA	Charlotte	26	88.46%
BMA of North Charlotte	BMA	Charlotte	40	98.75%
BMA West Charlotte	BMA	Charlotte	29	87.93%
FKC Mallard Creek*	BMA	Charlotte	0	0.00%
FMC Regal Oaks	BMA	Charlotte	12	43.75%
FKC Southeast Charlotte*	BMA	Charlotte	0	0.00%
FMC Aldersgate*	BMA	Charlotte	0	0.00%
FMC Charlotte	BMA	Charlotte	44	89.20%
FMC Matthews	BMA	Matthews	21	115.48%
FMC Southwest Charlotte	BMA	Charlotte	13	84.62%
Brookshire Dialysis*	DaVita	Charlotte	0	0.00%
Carolinas Medical Center	CMC	Charlotte	9	25.00%
Charlotte Dialysis	DaVita	Charlotte	36	86.11%
Charlotte East Dialysis	DaVita	Charlotte	34	90.44%
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	69.79%
DSI Glenwater Dialysis	DSI	Charlotte	42	75.00%
Huntersville Dialysis	DaVita	Huntersville	14	83.93%
Mint Hill Dialysis	DaVita	Mint Hill	16	84.38%
North Charlotte Dialysis Center	DaVita	Charlotte	37	68.24%
South Charlotte Dialysis**	DaVita	Charlotte	23	83.70%
South Charlotte Dialysis*	DaVita	Charlotte	0	0.00%
Sugar Creek Dialysis*	DaVita	Charlotte	0	0.00%

Source: July 2018 SDR, Table B.

* Facility under development.

**Per Project I.D. #F-11323-17, this facility is being relocated to a new location.

In Section N.1, page 58, 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 58, the applicant states:

“FMC Regal Oaks does not expect this proposal to have effect on the competitive climate in Mecklenburg County. All of the dialysis facilities in Mecklenburg County are operated by Fresenius Medical Care, parent to FMC Regal Oaks. BMA does not project to serve dialysis patients currently being served by another provider in a contiguous county. The projected patient population for the FMC Regal Oaks facility begins with patients currently served by BMA, and a growth of that patient population using a three year average annual change rate of 10.0% for the Mecklenburg County patients.”

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
- 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 5, the applicant states that BMA is a wholly owned subsidiary of Fresenius Medical Care Holdings (FMCH), Inc. In Exhibit A.4, the applicant provides a list of its North Carolina dialysis facilities.

In Section O, page 62, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in none of these facilities. The applicant states in Section O.3, page 62 that all facilities are currently in compliance with all Medicare conditions of participation. After reviewing and considering information provided by the applicant and considering the quality of care provided at all 114 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

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

10 NCAC 14C .2203 PERFORMANCE STANDARDS

.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- FMC Regal Oaks is an existing facility.

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

-C- In Section C, pages 13-15, the applicant demonstrates that FMC Regal Oaks will serve a total of 50 in-center patients at the end of OY1 for a utilization rate of 83.33% or 3.33 patients per station per week (50 patients / 15 stations = 3.3333 / 4 = 0.8333 or 83.33%). The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

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

- C- In Section C.1, pages 13 -15, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.