

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 6, 2019

Findings Date: December 6, 2019

Project Analyst: Julie M. Faenza

Team Leader: Gloria C. Hale

Project ID #: F-11775-19

Facility: Fresenius Kidney Care Regal Oaks

FID #: 150024

County: Mecklenburg

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

Project: Add no more than 2 dialysis stations for a total of no more than 17 stations upon project completion

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications of North Carolina, Inc. (BMA or “the applicant”) proposes to add two dialysis stations to Fresenius Kidney Care Regal Oaks (FKC Regal Oaks) for a total of 17 dialysis stations at FKC Regal Oaks upon project completion.

Need Determination

The 2019 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 the July 2019 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of 22 dialysis stations in Mecklenburg County. Therefore, the July 2019 SDR does not indicate a need for additional stations in Mecklenburg County based on the county need methodology. However, the applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most

recent SDR, is at least 3.2 patients per station per week, or 80 percent. The utilization rate reported for FKC Regal Oaks in the July 2019 SDR is 3.75 patients per station per week, or 93.75 percent, based on 45 in-center dialysis patients and 12 certified dialysis stations [$45 / 12 = 3.75$; $3.75 / 4 = 0.9375$ or 93.75%].

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

OCTOBER 1 REVIEW – JULY 2019 SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/18		93.75%
Certified Stations		15
Pending Stations		0
Total Existing and Pending Stations		15
In-Center Patients as of 12/31/18 (July 2019 SDR) (SDR2)		45
In-Center Patients as of 6/30/18 (January 2019 SDR) (SDR1)		34
Step	Description	Result
	Difference (SDR2 - SDR1)	11
(i)	Multiply the difference by 2 for the projected net in-center change	22
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/18	0.6471
(ii)	Divide the result of Step (i) by 12	0.0539
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/17 until 12/31/18)	0.6471
(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	74.1176
(v)	Divide the result of Step (iv) by 3.2 patients per station	23.1618
	and subtract the number of certified and pending stations to determine the number of stations needed	8

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is eight stations. Rounding to the nearest whole number is allowed in Step (v) of the facility need methodology, as stated in the July 2019 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 two new stations and is therefore consistent with the facility need determination for dialysis stations.

Policies

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

“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall

document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

Promote Safety and Quality

The applicant describes how it believes the proposed project will promote safety and quality in Section B, page 12; Section N, pages 53-55; Section O, pages 56-59; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project will promote equitable access in Section B, pages 12-13; Section C, pages 21-22; Section L, pages 48-51; Section N, pages 53-55; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project will maximize healthcare value in Section B, pages 13-14; Section C, pages 18-20; Section F, pages 29-33; Section K, pages 44-45; Section N, pages 53-55; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will maximize healthcare value.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

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

(2) Repealed effective July 1, 1987.

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

C

The applicant proposes to add two dialysis stations to FKC Regal Oaks for a total of 17 dialysis stations upon project completion.

FKC Regal Oaks does not currently offer home hemodialysis training or home peritoneal dialysis training and does not plan to offer either type of training following completion of the proposed project.

Patient Origin

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

In Section C, page 17, the applicant states that on December 31, 2018, it was serving 45 Mecklenburg County patients. On Form C in Section Q, the applicant projects to serve 55.6 Mecklenburg County patients by the end of the first full operating year following project completion (CY 2021). In Section C, pages 18-19, the applicant provides the assumptions and methodology used to project patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 19-20, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

“Patients with End Stage Renal Disease require dialysis treatment on a regular and consistent basis in order to maintain life. As a general rule, patients will receive three treatments per week. The NC SMFP recognizes that this patient population requires frequent and regular treatment. ... Failure to receive dialysis care will ultimately lead to the patient’s demise.

The need that this population has for the proposed services is a function of the individual patient need for dialysis care and treatment. This question specifically addresses the need that the population to be served has for the proposed project. BMA has identified the population to be served as 55.6 in-center dialysis patients dialyzing with the facility as of the end of the first Operating Year of the project.”

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

- According to the July 2019 SDR, as of December 31, 2018, FKC Regal Oaks was operating at a rate of 3.75 patients per station per week, or 93.75 percent of capacity.
- The applicant demonstrates eligibility to add dialysis stations to its facility via the facility need methodology. The discussion regarding need methodology found in Criterion (1) is incorporated herein by reference.

Projected Utilization

In Section C, page 17, the applicant states that on December 31, 2018, it was serving 45 Mecklenburg County patients. On Form C in Section Q, the applicant projects to serve 55.6 Mecklenburg County patients by the end of the first full operating year following project completion (CY 2021).

In Section C, pages 18-19, the applicant provides the assumptions and methodology used to project patient utilization, which are summarized below.

- The applicant begins its utilization projections with the patient facility census as of June 30, 2019. On page 18, the applicant states that, as of June 30, 2019, it was serving 48 Mecklenburg County patients.
- The applicant states the Mecklenburg County Five Year Average Annual Change Rate (AACR), as published in the July 2019 SDR, is 4.2 percent; however, the applicant states FKC Regal Oaks has been growing faster than the Mecklenburg County Five Year AACR. The applicant states that between December 31, 2017 and June 30, 2019, the patient census increased from 21 patients to 48 patients – an increase of 27 patients. The applicant states it does not believe that rate of growth will continue, and projects patient utilization based on a six percent annual growth rate. The Project Analyst believes a six percent annual growth rate is reasonable and adequately supported, especially considering the patient census at FKC Regal Oaks more than doubled in the space of a single year – from 21 patients on December 31, 2017 to 45 patients on December 31, 2018.
- The project is scheduled for completion on December 31, 2020. OY1 is CY 2021. OY2 is CY 2022.

In Section C, page 19, the applicant provides the calculations used to project the patient census for OY1 and OY2, as summarized in the table below.

FKC Regal Oaks Projected Utilization	
Starting point of calculations is Mecklenburg County patients dialyzing at FKC Regal Oaks on June 30, 2019.	48
Mecklenburg County patient population is projected forward by six months to December 31, 2019, using one-half of the applicant's projected growth rate (6.0%).	$48 \times 1.03 = 49.4$
Mecklenburg County patient population is projected forward by one year to December 31, 2020, using the applicant's projected growth rate (6.0%). This is the projected census on December 31, 2020 and the starting census for this project.	$49.4 \times 1.06 = 52.4$
Mecklenburg County patient population is projected forward by one year to December 31, 2021, using the applicant's projected growth rate (6.0%). This is the projected census on December 31, 2021 (OY1).	$52.4 \times 1.06 = 55.6$
Mecklenburg County patient population is projected forward by one year to December 31, 2022, using the applicant's projected growth rate (6.0%). This is the projected census on December 31, 2022 (OY2).	$55.6 \times 1.06 = 58.9$

The applicant projects to serve 55.6 in-center patients on 17 stations, which is 3.27 patients per station per week ($55.6 \text{ patients} / 17 \text{ stations} = 3.27$), by the end of OY1 and 58.9 in-center patients on 17 stations, which is 3.46 patients per station per week ($58.9 \text{ patients} / 17 \text{ stations} = 3.46$), by the end of OY2. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

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

- According to the July 2019 SDR, as of December 31, 2018, FKC Regal Oaks was operating at a rate of 3.75 patients per station per week, or 93.75 percent of capacity.
- The applicant projects future utilization based on historical utilization.
- The applicant provides adequate documentation to support its use of a growth rate higher than the Five Year AACR for Mecklenburg County of 4.2 percent as published in the July 2019 SDR.
- The applicant's projected utilization exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

Access

In Section C, page 21, the applicant states:

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

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

In Section L, page 50, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

FKC Regal Oaks Projected Payor Mix CY 2022		
Payment Source	# Patients	% Patients
Self-Pay	4.03	6.84%
Commercial Insurance*	9.16	15.55%
Medicare*	33.79	57.38%
Medicaid*	3.77	6.40%
Medicare/Commercial	4.40	7.47%
Misc. (including VA)	3.74	6.36%
Total	58.88	100.00%

*Including any managed care plans

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 a service, eliminate a service, or 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

The applicant proposes to add two dialysis stations to FKC Regal Oaks for a total of 17 dialysis stations upon project completion.

In Section E, pages 27-28, 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 maintaining the status quo would lead to higher utilization rates and fewer opportunities for admission; therefore, this is not an effective alternative.
- **Apply for Fewer than Two Stations:** the applicant states the facility need methodology indicates a need for more than two stations and the applicant projects a utilization rate above 80 percent by the end of the first operating year. The applicant states applying for fewer stations would lead to higher utilization rates and fewer opportunities for admission; therefore, this is not an effective alternative.
- **Relocate Stations from Another Mecklenburg County Facility:** the applicant states that, as of December 31, 2018, all but two of its operational facilities serving in-center patients in Mecklenburg County were operating above 80 percent utilization. The applicant states that as of June 30, 2019, all but one of its facilities in Mecklenburg County were operating above 80 percent utilization. The applicant states the one facility with less than 80 percent utilization is a new facility and has a patient census that more than doubled in the six months since it first reported patients; therefore, this is not an effective alternative.

On page 28, the applicant states its proposal is the most effective alternative because it is a cost-effective approach and is necessary to meet the need for dialysis patients in Mecklenburg County.

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

- The application is conforming to all statutory and regulatory review criteria.

- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

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

- 1. Bio-Medical Applications of North Carolina, Inc. shall materially comply with all representations made in the certificate of need application.**
 - 2. Pursuant to the facility need determination in the July 2019 Semiannual Dialysis Report, Bio-Medical Applications of North Carolina, Inc. shall develop no more than two additional dialysis stations at Fresenius Kidney Care Regal Oaks for a total of no more than 17 certified stations at Fresenius Kidney Care Regal Oaks upon completion of this project, which shall include any home hemodialysis training or isolation stations.**
 - 3. Bio-Medical Applications of North Carolina, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to add two dialysis stations to FKC Regal Oaks for a total of 17 dialysis stations upon project completion.

Capital and Working Capital Costs

On Form F.1a in Section Q, the applicant projects a capital cost of \$7,500 to develop the project, to be used for dialysis stations and associated equipment. In Section F, page 30, the applicant states there are no projected start-up expenses or initial operating expenses because it is an existing, operational facility.

Availability of Financing

In Section F, page 29, the applicant states the capital costs for the proposed project will be financed through accumulated reserves. Exhibit F-2 contains a letter from the Senior Vice President and Treasurer of Fresenius Medical Care Holdings, Inc., the applicant's parent company, authorizing the use of accumulated reserves for the capital needs of the project.

The letter in Exhibit F-2 further states:

“This project is to be funded through Fresenius Medical Care Holdings, Inc., accumulated reserves. Our 2018 Consolidated Balance Sheet reflects more than \$1.8 billion in cash, and total assets exceeding \$20 billion.”

Financial Feasibility

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

Projected Revenues and Operating Expenses		
FKC Regal Oaks	Full Fiscal Year 1 CY 2021	Full Fiscal Year 2 CY 2022
Total Treatments	7,988.83	8,468.16
Total Gross Revenues (Charges)	\$50,257,740	\$53,273,204
Total Net Revenue	\$2,663,802	\$2,823,630
Average Net Revenue per Treatment	\$333	\$333
Total Operating Expenses (Costs)	\$2,613,413	\$2,707,396
Average Operating Expense per Treatment	\$327	\$320
Net Income/Profit	\$50,388	\$116,234

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

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
 - The applicant adequately demonstrates 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.

C

The applicant proposes to add two dialysis stations to FKC Regal Oaks for a total of 17 dialysis stations upon project completion.

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

According to Tables B and C of the July 2019 SDR, there are 26 facilities which provide dialysis and/or dialysis home training and support in Mecklenburg County, 23 of which are operational. Information on all 26 of these dialysis facilities, from Tables B and C of the July 2019 SDR, is provided below:

Mecklenburg County Dialysis Facilities Certified Stations and Utilization as of December 31, 2018				
Dialysis Facility	Owner	Location	# of Certified Stations	Utilization
BMA Beatties Ford	BMA	Charlotte	32	95.31%
BMA Nations Ford	BMA	Charlotte	28	79.46%
BMA of East Charlotte	BMA	Charlotte	26	89.42%
BMA West Charlotte	BMA	Charlotte	29	87.93%
FKC Mallard Creek*	BMA	Charlotte	0	0.00%
FKC Regal Oaks	BMA	Charlotte	12	93.75%
FKC Southeast Charlotte*	BMA	Pineville	0	0.00%
FMC Aldersgate	BMA	Charlotte	10	27.50%
FMC Charlotte	BMA	Charlotte	44	89.20%
FMC Matthews	BMA	Matthews	21	114.29%
FMC of North Charlotte	BMA	Charlotte	40	96.88%
FMC Southwest Charlotte	BMA	Charlotte	13	92.31%
INS Charlotte**	BMA	Charlotte	0	0.00%
INS Huntersville**	BMA	Huntersville	0	0.00%
Brookshire Dialysis	DaVita	Charlotte	10	40.00%
Carolinas Medical Center	CMC	Charlotte	9	33.33%
Charlotte Dialysis	DaVita	Charlotte	34	81.62%
Charlotte East Dialysis	DaVita	Charlotte	34	80.15%
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	67.71%
DSI Glenwater Dialysis	DSI	Charlotte	42	74.40%
Huntersville Dialysis	DaVita	Huntersville	14	92.86%
Mint Hill Dialysis	DaVita	Mint Hill	22	55.68%
Mountain Island Lake Dialysis*	DaVita	Charlotte	0	0.00%
North Charlotte Dialysis Center	DaVita	Charlotte	36	72.92%
South Charlotte Dialysis***	DaVita	Charlotte	23	85.87%
South Charlotte Dialysis***	DaVita	Charlotte	0	0.00%
Sugar Creek Dialysis	DaVita	Charlotte	10	50.00%

Source: July 2019 SDR, Tables B and C.

* Facility under development or which was not operational at the time of data collection for the July 2019 SDR.

**Facility which is dedicated exclusively to providing HH and PD training and support.

***Per Project I.D. #F-11323-17, this facility is being relocated to a new location; the July 2019 SDR lists both the existing operational facility and the replacement facility.

In Section G, pages 35-36, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Mecklenburg County. On page 36, the applicant states:

“The July 2019 SDR does report a surplus of 22 dialysis stations in Mecklenburg County. The SDR also reports that the Mecklenburg County ESRD Census for December 31, 2018 was 1,792, and that this census was increasing at a rate of 4.2%. The growth of the Mecklenburg County ESRD patient population results in a projection of 75.6 new dialysis patients for 2019. If this growth rate is sustained, (and there is no indication that the growth rate will not be sustained), and assuming the home patient [sic] population percentage remains the same, Mecklenburg County will need 21 new

dialysis stations each year (at 80% utilization). The current surplus of stations will be quickly eroded.

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

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

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

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

On Form H in Section Q, the applicant provides information about current and projected staffing for the proposed services. The applicant does not project to change its staffing levels in response to the proposed project.

Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.4, which is found in Section Q. In Section H, page 38, the applicant describes the methods it uses to recruit or fill new positions and its existing training and continuing education programs. The applicant provides supporting documentation in Exhibits H-3.1 and H-3.2. In Section H, page 39, the applicant identifies the current medical director. In Exhibit H-4, the applicant provides a letter from the current medical director expressing his support for the proposed project and indicating his intent to continue serving as medical director for the facility.

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, pages 40-41, the applicant states the following ancillary and support services are necessary for the proposed services, and explains how each ancillary and support service is made available:

FKC Regal Oaks – Ancillary and Support Services	
Services	Provider
In-center dialysis/maintenance	On site
Self-care training (in-center)	Referral to FMC Charlotte or INS Charlotte
Home training HH PD Accessible follow-up program	Referral to FMC Charlotte or INS Charlotte Referral to FMC Charlotte or INS Charlotte Referral to FMC Charlotte or INS Charlotte
Psychological counseling	Referral to Serendipity Therapy Services, Carolinas Medical Center
Isolation – hepatitis	On site
Nutritional counseling	On site
Social Work services	On site
Acute dialysis in an acute care setting	Carolinas Medical Center
Emergency care	Provided by facility staff until ambulance arrival
Blood bank services	Carolinas Medical Center
Diagnostic and evaluation services	Carolinas Medical Center
X-ray services	Carolinas Medical Center
Laboratory services	On site (Spectra)
Pediatric nephrology	Carolinas Medical Center
Vascular surgery	Metrolina Vascular Access Center, Surgical Specialists of Charlotte, Sanger Heart and Vascular
Transplantation services	Carolinas Medical Center
Vocational rehabilitation & counseling	Carolinas Medical Center Rehabilitation
Transportation	Charlotte Area Transportation, Medicaid Transport Services, Special Transportation Services

The applicant provides supporting documentation in Exhibits I-1 through I-4.

In Section I, page 41, the applicant describes its existing relationships with other local health care and social service providers.

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 or renovate any 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, page 49, the applicant provides the historical payor mix during CY 2018 for its existing services, as shown in the table below.

FKC Regal Oaks Historical Payor Mix CY 2018		
Payment Source	# Patients	% Patients
Self-Pay	3.08	6.84%
Commercial Insurance*	7.00	15.55%
Medicare*	25.82	57.38%
Medicaid*	2.88	6.40%
Medicare/Commercial	3.36	7.47%
Misc. (including VA)	2.86	6.36%
Total	45.00	100.00%

*Including any managed care plans

In Section L, page 48, the applicant provides the following comparison.

	Percentage of Total Patients Served by FKC Regal Oaks during the Last Full OY	Percentage of the Population of Mecklenburg County
Female	38.6%	51.9%
Male	61.4%	48.1%
Unknown	0.0%	0.0%
64 and Younger	72.7%	88.8%
65 and Older	27.3%	11.2%
American Indian	0.0%	0.8%
Asian	2.3%	6.4%
Black or African-American	61.4%	32.9%
Native Hawaiian or Pacific Islander	6.8%	0.1%
White or Caucasian	29.5%	46.4%
Other Race	0.0%	13.4%
Declined / Unavailable	0.0%	0.0%

Sources: BMA Internal Data, US Census Bureau

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 applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, the applicant states in Section L, pages 49-50, that it has no obligation by any of its facilities to provide uncompensated care or community service under any federal regulations.

In Section L, page 50, 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 50, 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.

FKC Regal Oaks Projected Payor Mix CY 2022		
Payment Source	# Patients	% Patients
Self-Pay	4.03	6.84%
Commercial Insurance*	9.16	15.55%
Medicare*	33.79	57.38%
Medicaid*	3.77	6.40%
Medicare/Commercial	4.40	7.47%
Misc. (including VA)	3.74	6.36%
Total	58.88	100.00%

*Including any managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 6.84 percent of services will be provided to self-pay patients; 64.85 percent to patients who will have some or all of their care paid for by Medicare (includes Medicare/commercial); and 6.40 percent to Medicaid patients.

On pages 50-51, the applicant provides the assumptions and methodology it uses 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 for the following reasons:

- The projected payor mix is based on the historical payor mix.
- Projected utilization is reasonable and adequately supported. 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.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section L, page 51, the applicant adequately describes the range of means by which patients will have access to 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.

- (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 52, 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-2.

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 add two dialysis stations to FKC Regal Oaks for a total of 17 dialysis stations upon project completion.

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

According to Tables B and C of the July 2019 SDR, there are 26 facilities which provide dialysis and/or dialysis home training and support in Mecklenburg County, 23 of which are operational. Information on all 26 of these dialysis facilities, from Tables B and C of the July 2019 SDR, is provided below:

Mecklenburg County Dialysis Facilities Certified Stations and Utilization as of December 31, 2018				
Dialysis Facility	Owner	Location	# of Certified Stations	Utilization
BMA Beatties Ford	BMA	Charlotte	32	95.31%
BMA Nations Ford	BMA	Charlotte	28	79.46%
BMA of East Charlotte	BMA	Charlotte	26	89.42%
BMA West Charlotte	BMA	Charlotte	29	87.93%
FKC Mallard Creek*	BMA	Charlotte	0	0.00%
FKC Regal Oaks	BMA	Charlotte	12	93.75%
FKC Southeast Charlotte*	BMA	Pineville	0	0.00%
FMC Aldersgate	BMA	Charlotte	10	27.50%
FMC Charlotte	BMA	Charlotte	44	89.20%
FMC Matthews	BMA	Matthews	21	114.29%
FMC of North Charlotte	BMA	Charlotte	40	96.88%
FMC Southwest Charlotte	BMA	Charlotte	13	92.31%
INS Charlotte**	BMA	Charlotte	0	0.00%
INS Huntersville**	BMA	Huntersville	0	0.00%
Brookshire Dialysis	DaVita	Charlotte	10	40.00%
Carolinas Medical Center	CMC	Charlotte	9	33.33%
Charlotte Dialysis	DaVita	Charlotte	34	81.62%
Charlotte East Dialysis	DaVita	Charlotte	34	80.15%
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	67.71%
DSI Glenwater Dialysis	DSI	Charlotte	42	74.40%
Huntersville Dialysis	DaVita	Huntersville	14	92.86%
Mint Hill Dialysis	DaVita	Mint Hill	22	55.68%
Mountain Island Lake Dialysis*	DaVita	Charlotte	0	0.00%
North Charlotte Dialysis Center	DaVita	Charlotte	36	72.92%
South Charlotte Dialysis***	DaVita	Charlotte	23	85.87%
South Charlotte Dialysis***	DaVita	Charlotte	0	0.00%
Sugar Creek Dialysis	DaVita	Charlotte	10	50.00%

Source: July 2019 SDR, Tables B and C.

* Facility under development or which was not operational at the time of data collection for the July 2019 SDR.

**Facility which is dedicated exclusively to providing HH and PD training and support.

***Per Project I.D. #F-11323-17, this facility is being relocated to a new location; the July 2019 SDR lists both the existing operational facility and the replacement facility.

In Section N, pages 53-55, 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 53, the applicant states:

“The applicant does not expect this proposal to have any effect on the competitive climate in Mecklenburg County. The applicant does not project to serve dialysis patients currently being served by another provider. ...

...

Fresenius [the parent company of the applicant] related facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients. Every effort is made to (a) ensure that the applicant thoroughly plans for the success of a facility prior to the application, and, (b) that once the project is completed, all staff members work toward the clinical and financial success of the facility. This proposal will certainly not adversely affect quality, but rather, enhance the quality of the ESRD patients' lives by offering a convenient venue for dialysis care and treatment, and promoting access to care."

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 Q 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 Sections C and L of the application and any exhibits).

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.

- (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

On Form A in Section Q, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 127 existing or approved kidney disease treatment facilities located in North Carolina.

In Section O, page 59, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents related to quality of care resulting in an immediate jeopardy violation that occurred in any of these facilities. After reviewing and

considering information provided by the applicant and publicly available data and considering the quality of care provided at all 127 facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

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

C

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

10 NCAC 14C .2203 PERFORMANCE STANDARDS

- (a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*
- NA- FKC Regal Oaks is an existing facility. Therefore, this Rule is not applicable to this review.
- (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, page 19, the applicant projects that FKC Regal Oaks will serve 55.6 patients on 17 stations, or a rate of 3.27 patients per station per week, as of the end of the first operating year following project completion. 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 18-19, the applicant provides the assumptions and methodology it uses to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.