

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: October 8, 2025

Findings Date: October 8, 2025

Project Analyst: Chalice L. Moore

Co-Signer: Mike McKillip

Project ID #: F-12668-25

Facility: Fresenius Kidney Care Regal Oaks

FID #: 150024

County: Mecklenburg

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

Project: Add no more than two in-center dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 23 stations upon project completion

REVIEW CRITERIA

G.S. 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. (hereinafter referred to as “BMA” or “the applicant”) proposes to add no more than two dialysis stations at Fresenius Kidney Care Regal Oaks (FKC Regal Oaks) pursuant to Condition 2 of the facility need methodology for a total of no more than 23 dialysis stations upon project completion.

Need Determination (Condition 2)

Chapter 9 of the 2025 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table 9B, the county need methodology shows there is no county need determination for additional dialysis stations in Mecklenburg County.

However, the applicant is eligible to apply for additional dialysis stations in an existing facility pursuant to Condition 2 of the facility need methodology in the 2025 SMFP, if the utilization rate for the facility as reported in the 2025 SMFP is at least 75 percent or 3.0 patients per station per week, as stated in Condition 2.a. The utilization rate reported for the facility is 88.24% or 3.53 patients per station per week, based on 60 in-center dialysis patients and 17 certified dialysis stations (60 patients /17 stations = 3.53, 3.53 / 4 = 88.25%).

The applicant proposes to add no more than two dialysis station to the facility, which is consistent with the 2025 SMFP calculated facility need determination for up to two stations; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

Policies

There is one policy in the 2025 SMFP that is applicable to this review, Policy GEN-5: Basic Principles.

Policy GEN-5 states:

“Access to Culturally Competent Healthcare A certificate of need (CON) applicant applying to offer or develop 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 provide culturally competent healthcare that integrates principles to increase health equity and reduce health disparities in underserved communities. The delivery of culturally competent healthcare requires the implementation of systems and training to provide responsive, personalized care to individuals with diverse backgrounds, values, beliefs, customs, and languages. A certificate of need applicant shall identify the underserved populations and communities it will serve, including any disparities or unmet needs of either, document its strategies to provide culturally competent programs and services, and articulate how these strategies will reduce existing disparities as well as increase health equity.”

Demographics

In Section B, page 21, and Exhibit B.1, the applicant describes how the proposed project will focus on the medically underserved communities within the service area. The applicant states that the proposed service area is Mecklenburg County. The information provided by the applicant is reasonable and supports the determination that the applicant’s relevant service area with a specific focus on the medically underserved communities within that service area.

Culturally Competent Services

In Section B, page 22, the applicant states that Fresenius Kidney Care (FKC) has developed a Health Equity Strategic Plan that outlines organizational goals, objectives, actions, and resources to ensure that as an organization, they are providing culturally competent services to all members of the medically underserved community who are receiving services within FKC

or FKC facilities. The information provided by the applicant is reasonable and supports the determination that the applicant's proposal will provide culturally competent services to members of the medically underserved community.

Reflect Cultural Competence

In Section B, page 23, the applicant states the following:

“The delivery of culturally competent healthcare requires the implementation of systems and training to provide responsive, personalized care to individuals with diverse backgrounds, values, beliefs, customs, and language”

The information provided by the applicant is reasonable and supports the determination that the applicant's proposal will provide culturally competent services to members of the medically underserved community.

Reducing Health Disparities

In Section B, page 24, the applicant describes how the proposed project will focus on prioritizing health equity within the service area. The applicant states that the proposed service area is Mecklenburg County. The information provided by the applicant is reasonable and supports the determination that the applicant's relevant service area with a specific focus on the medically underserved communities within that service area.

Increase Equitable Access

In Section B, page 24, the applicant describes how the proposed project will measure and periodically assess increased equitable access to healthcare services and reduction in health disparities in underserved communities within the service area. The applicant states that the proposed service area is Mecklenburg County. The information provided by the applicant is reasonable and supports the determination that the applicant's relevant service area with a specific focus on the medically underserved communities within that service area.

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 based on the following:

- The applicant adequately demonstrates that the application is consistent with Condition 2 of the facility need methodology as applied from the 2025 SMFP.
- The applicant adequately demonstrates that the application is consistent with Policy GEN-5 based on the projects proposed incorporation of access to culturally competent healthcare.

- (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, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C

FKC Regal Oaks proposes to add no more than two in-center dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 23 stations upon project completion

Patient Origin

On page 113, the 2025 SMFP defines the service area for dialysis stations as “*the county in which the dialysis station is located*”. Thus, the service area for this facility consists of Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates historical and projected patient origin for in-center (IC) patients, Home Hemodialysis (HH), and Peritoneal Dialysis (PD) training and support services. The applicant states FKC Regal Oaks was certified for home dialysis effective January 20, 2025 and currently offers both home hemodialysis (HH) and peritoneal dialysis (PD) training and support services.

FKC Regal Oaks												
	Historical – CY 2024						Projected – CY 2028					
	IC Patients		HH Patients		PD Patients		IC Patients		HH Patients		PD Patients	
	#	%	#	%	#	%	#	%	#	%	#	%
Mecklenburg	48.0	100.0%					72.1	98.6%	6.0	100.0%	5.0	100.0%
Lincoln							1.0	1.4%				
Total	48.0	100.0%					73.1	100%	6.0	100.0%	5.0	100.0%

In Section C, pages 25-26, and the Form C Utilization subsection of Section Q page 84, the applicant provides the assumptions and methodology used to project patient origin. The applicant’s assumptions are reasonable and adequately supported because they are based on the historical (CY2024) patient origin for the facility.

Analysis of Need

In Section C, page 32, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

“The need that this population has for the proposed services is a function of the individual patient’s need for dialysis care and treatment. This question specifically addresses the need that the population to be served has for the proposed project. The applicant has identified the population to be served as 66.8 in-center dialysis patients dialyzing with the facility as of the end of the first Operating Year of the project. This equates to a utilization rate of 72.65%, or 2.91 patients per station and exceeds the minimum required by the performance standard.”

The information is reasonable and adequately supported based on the following:

- The applicant demonstrates eligibility to add dialysis stations to its facility under Condition 2 of the facility need methodology, as stated in the 2025 SMFP. The discussion regarding need methodology found in Criterion (1) is incorporated herein by reference.
- The applicant adequately demonstrates need based on the facility’s historical and projected growth in the patient population, as described on pages 26-28 of the application.

Projected Utilization

In-Center Utilization

In Section C, pages 29-30, and in Form Utilization C, Section Q, pages 88-89, the applicant provides the projected in-center utilization for FKC Regal Oaks, as illustrated in the following table:

FKC Regal Oaks	In-Center patients
Begin with the Mecklenburg County patient population as of June 30, 2025.	54.0
Project the Mecklenburg County patient population forward 1 year to December 31, 2025, using the facility's historical growth rate for Mecklenburg County patients.	$54.0 \times \{(0.125/12) \times 6\} + 54 = 57.4$
Subtract the two in-center patients projected to convert to home dialysis.	$57.4 - 2.0 = 55.4$
Add the patients from other counties. This is the projected ending census for Interim Year 1	$55.4 \times 0.125 = 62.3$
Project the Mecklenburg County patient population forward to December 31, 2026, using the facility's historical growth rate for Mecklenburg County patients.	$55.4 \times 0.125 = 62.3$
Subtract the two in-center patients projected to convert to home dialysis.	$62.3 - 2.0 = 60.3$
Add the patients from other counties. This is the projected ending census Operating Year 2.	$60.3 + 1.0 = 61.3$
Project the Mecklenburg County patient population forward to December 31, 2027, using the facility's historical growth rate for Mecklenburg County patients.	$60.3 \times 0.125 = 67.8$
Subtract the two in-center patients projected to convert to home dialysis	$67.8 - 2.0 = 65.8$
Add the patients from other counties and South Carolina. This is the projected ending census Operating Year 1.	$65.8 + 1.0 = 66.8$
Project the Mecklenburg County patient population forward to December 31, 2028, using the facility's historical growth rate for Mecklenburg County patients	$65.8 \times 0.125 = 74.1$
Subtract the two in-center patients projected to convert to home dialysis.	$74.1 - 2.0 = 72.1$
Add the patients from other counties. This is the projected ending census Operating Year 2.	$72.1 + 1.0 = 73.1$

Source: Section C, pages 26-28

In Section C, pages 26-27, and in the Form C Utilization subsection of Section Q, page 84-87, the applicant provides the assumptions and methodology used to project patient utilization, which are summarized below.

- The 2025 SMFP, Table 9D indicates that FKC Regal Oaks qualifies to apply for up to two additional dialysis stations pursuant to Condition 2 of the Facility Need Methodology.
- The 2025 SMFP, Table 9A: Inventory of Dialysis Stations and calculation of utilization rates, column G, shows that FKC Regal oaks had four stations for which CON had been issued but were not yet certified.

- The applicant begins its utilization projections with the patient census on June 30, 2025, which is identified in the table below:

FKC Regal Oaks Patient Census as of 6/30/2025			
	ICHD	HHD	PD
Mecklenburg	54.0	2.0	1.0
Cleveland	1.0		
Lincoln	1.0		
Total	56.0	2.0	1.0

The table below shows the growth in both the total in-center patient population as well as Mecklenburg County in-center patient population at the facility between December 31, 2024, and June 30, 2025. The applicant uses a 12.5% growth rate commensurate with the facility’s recent experience to project future Mecklenburg County patient population at the facility rather than the Five-year Average Annual Change Rate (5-Year AACR) for Mecklenburg County in the 2025 SMFP which is 0.0%, as shown in the table below:

FKC Regal Oaks			
	12/31/2024	6/30/2025	Growth
Total ICHD Patients	48	56	16.7%
Total Mecklenburg County ICHD Patients	48	54	12.5%

- The applicant states that new referral to the facility, as well as facilities in close proximity will add in the increase in utilization of the facility. The applicant states that four of the five facilities were operating at 80% utilization as of December 31, 2024
- FKC Regal Oaks was certified for home dialysis on January 20, 2025 pursuant to CON Project ID # F-12136-21. The applicant believes that the two in-center will convert to home therapy (one HH and PD) each year going forward.
- As of June 30, 2025 the facility was serving one in-center patient from Cleveland County and one in-center patient from Lincoln County. Lincoln County is contiguous to Mecklenburg County. Therefore, the applicant concludes that this patient will continue dialysis at this facility as a function of patient choice. The applicant will not project growth in this segment of the patient population, but this patient will be added to future projections when appropriate.
- The new stations are projected to be certified as of December 31, 2026. Therefore, Operating Year 1 is the period from January 1- December 31, 2027, and Operating Year 2 is the period from January 1- December 31, 2028.

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

- The applicant bases the projections of the future patient population to be served at the facility based on actual patient census as of June 30, 2025.
- The applicant projects growth based on a 12.5% growth rate which is commensurate with the facility’s recent experience to project future Mecklenburg County patient population at the facility.

Home Dialysis Methodology

In Section C, pages 30-31, and in the Form C Utilization subsection of Section Q, page 84-87, the applicant provides the assumptions and methodology used to project patient utilization, for dialysis reviews, which are summarized below.

FKC Regal Oaks	HHD	PD
Begin with the Mecklenburg County patient population as of June 30, 2025.	2.0	2.0
Project the Mecklenburg County patient population forward 6 months to December 31, 2025, using the Mecklenburg County 5-Year AACR	$2.0 \times \{(0.0/12) \times 6\} + 2.0 = 2.0$	$1.0 \times \{(0.0/12) \times 6\} + 1 = 1.0$
Add the patients to be converted from in-center to home dialysis. This is the projected ending census for Interim Year 1.	$2.0 + 1.0 = 3.0$	$1.0 + 1.0 = 2.0$
Project the Mecklenburg County patient population forward 6 months to December 31, 2026, using the Mecklenburg County 5-Year AACR	$\{3.0 \times 0.0\} + 3.0 = 3.0$	$\{2.0 \times 0.0\} + 2.0 = 2.0$
Add the patients to be converted from in-center to home dialysis. This is the projected ending census for Interim Year 2.	$3.0 + 1.0 = 4.0$	$2.0 + 1.0 = 3.0$
Project the Mecklenburg County patient population forward to December 31, 2027, using the Mecklenburg County 5-Year AACR	$\{4.0 \times 0.0\} + 4.0 = 4.0$	$\{4.0 \times 0.0\} + 4.0 = 4.0$
Add the patients to be converted from in-center to home dialysis. This is the projected ending census for Operating Year 1.	$4.0 + 1.0 = 5.0$	$3.0 + 1.0 = 4.0$
Project the Mecklenburg County patient population forward to December 31, 2028, using the Mecklenburg County 5-Year AACR	$\{5.0 \times 0.0\} + 5.0 = 5.0$	$\{4.0 \times 0.0\} + 4.0 = 4.0$
Add the patients to be converted from in-center to home dialysis. This is the projected ending census for Operating Year 2.	$5.0 + 1.0 = 6.0$	$4.0 + 1.0 = 5.0$

Based upon the calculations, BMA projects to serve the following number of patients for Operating Years 1 & 2.

	Operating Year 1	Operating Year 2
In-Center	66.8	73.1
Home Hemodialysis	5.0	6.0
Peritoneal Dialysis	4.0	5.0

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

- The applicant bases the projections of the future patient population to be served at the facility based on actual patient census as of June 30, 2025.
- The applicant assumes two in-center patients will convert to home dialysis (one HH and one PD) each year based on the applicant’s historical experience.

Access to Medically Underserved Groups

In Section C, pages 31-32, 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 our corporate policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, or health insurer. ... Fresenius Medical Care and its related facilities in North Carolina have historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for being an underserved person.”

In Section C, pages 33-34, the applicant provides the estimated percentage of total patients to be served for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low-income persons	84.3%
Racial and ethnic minorities	92.2%
Women	45.1%
Persons with Disabilities	33.3%
Persons 65 and older	47.1%
Medicare beneficiaries	62.7%
Medicaid recipients	37.3%

Source: Section C, page 33-34

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the applicant’s history of providing services to medically underserved groups.

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 all the reasons described above.

- (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, ... persons [with disabilities], 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 services. 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.

C

FKC Regal Oaks proposes to add no more than two in-center dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 23 stations upon project completion

In Section E, page 42, the applicant states that there is no alternative method available to the applicant of meeting the needs of the proposal. The applicant states,

“Failure to apply for additional stations at FKC Regal Oaks would ultimately result in higher utilization rates. The applicant has demonstrated that the projected utilization for the end of operating year 1 is 2.91 patients per station; the projected utilization by the end of Operating Year 2 is 3.18 patients per station. These utilization rates are calculated based upon 21 dialysis stations...

If the applicant had chosen to not apply for additional stations, utilization on 21 dialysis stations would be projected to be 3.18 patients per station at the end of Operating Year 1 and 3.48 per station at the end of Operating Year 2.

...Failure to apply for additional stations leads to higher utilization rates, potentially interrupts patient admissions to the facility, would require an evening shift which may not be convenient or accessible for the patient and could thus be the least effective alternative than the selective alternative identified in this application.”

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

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 Facilities of North Carolina, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. Pursuant to Condition 2 of the facility need determination in the 2025 SMFP, the certificate holder shall develop no more than two additional in-center dialysis stations at FKC Regal Oaks for a total of no more than 23 in-center stations upon project completion.**
- 3. Progress Reports:**
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. The certificate holder shall complete all sections of the Progress Report form.**
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. The first progress report shall be due April 1, 2026.**
- 4. The certificate holder 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

FKC Regal Oaks proposes to add no more than two in-center dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 23 stations upon project completion

Capital and Working Capital Cost

In Section F, page 93, the applicant projects a capital cost of \$7,500, as shown in the table below. The assumptions used to project capital cost in Form F. 1a Capital Cost are provided in Section Q.

Capital Cost	
Non-Medical Equipment	\$1,500
Furniture	\$6,000
Total Capital Cost	\$7,500

Source: Section Q page 93

In Section F, page 42, the applicant states there are no projected working capital costs because it is an existing facility that is already operational.

Availability of Funds

In Section F, page 43, the applicant projects the sources of financing for the capital cost of the project, as shown in the table below.

Source of Financing for Capital Costs	Amount
Loans	\$0
Cash and Cash Equivalents Accumulated Reserves or OE*	\$7,500
Bonds	\$0
Other (Describe)	\$0
Total Financing	\$7,500

*OE= Owner's Equity Source: Section F, page 43.

In Exhibit F.2, the applicant provides documentation from the parent company, Fresenius Medical Care Holdings, Inc, VP of Corporate Tax North America, dated July 15, 2025, that the company has committed cash reserves sufficient to fund the proposed project.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the documentation provided in Exhibit F-2.

Financial Feasibility

The applicant provided pro forma financial statements for the first two full fiscal years of operation following completion of the project. In 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:

	CY2027 1st Full FY	CY2028 2nd Full FY
Total Treatment	10,666	11,882
Total Gross Revenues (Charges)	\$67,097,815	\$74,437,591
Total Net Revenue	\$4,250,828	\$4,749,949
Average Net Revenue per Treatment	\$399	\$400
Total Operating Expenses (Costs)	\$3,373,558	\$3,539,142
Average Operating Expense per Treatment	\$316	\$298
Net Income	\$877,271	\$1,210,806

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Forms F.2, F.3 and F.4 in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant adequately explains the assumptions used to project revenue, such as projected reimbursement rates, and operating costs, such as salaries.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which 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 for all the reasons described above.
 - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
 - 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.

FKC Regal Oaks proposes to add no more than two in-center dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 23 stations upon project completion

On page 113, the 2025 SMFP defines the service area for dialysis stations as “...*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” 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 Table 9A, pages 125-126 of the 2025 SMFP, there are 23 existing or approved dialysis facilities in Mecklenburg County, as shown in the following table:

Dialysis Facility	Certified Stations 12/31/2023	Number In-Center Patients 12/31/2023	Utilization
BMA Bettis Ford	43	87	50.58%
BMA Nations Ford	28	95	84.82%
BMA of East Charlotte	32	118	92.19%
BMA West Charlotte	29	77	66.38%
Brookshire Dialysis	20	46	57.50%
Charlotte Dialysis	33	98	74.24%
Charlotte East Dialysis	34	91	66.91%
DSI Charlotte Latrobe Dialysis	24	63	65.63%
DSI Glenwater Dialysis	42	92	54.76%
FMC Charlotte	48	85	44.27%
FMC Matthews	21	91	108.33%
FMC of North Charlotte	40	133	81.13%
Fresenius Kidney Care Charlotte	0	0	0.00%
Fresenius Kidney Care Huntersville	0	0	0.00%
Fresenius Kidney Care Mallard Creek	12	39	81.25%
Fresenius Kidney Care Regal Oaks	17	60	88.24%
Fresenius Kidney Care Southeast Mecklenburg	17	52	76.47%
Fresenius Medical Care Aldersgate	16	52	81.25%
Fresenius Medical Care Southwest Charlotte	26	71	68.27%
Huntersville Dialysis	27	78	72.22%
INS Victory Home (replacement for INS Charlotte)	7	0	0.00%
Mint Hill Dialysis	21	49	58.33%
North Charlotte Dialysis	33	83	62.88%
South Charlotte Dialysis	27	74	68.52%

Source: Table 9A in the 2025 SMFP.

In Section G, page 47, 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:

“This application is to develop two dialysis stations at FKC Regal Oaks pursuant to Condition 2 of the facility need methodology identified in Table 9D: Dialysis Station Need Determination by Facility in the 2025 SMFP. The need addressed by this

application is not specific to Mecklenburg County as a whole. The station is needed by the patient population projected to be served by the FKC Regal Oaks facility”.

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

- The applicant proposes to increase the number of dialysis stations at FKC Regal Oaks based on Condition 2 of the facility need determination in the 2025 SMFP.
- The applicant adequately demonstrates that the two proposed dialysis stations are needed in addition to the existing or approved dialysis stations in Mecklenburg County.

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 all the reasons described 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

FKC Regal Oaks proposes to add no more than two in-center dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 23 stations upon project completion

In Section Q, Form H, page 95, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table:

Position	Projected FTE Staff	Projected FTE Staff
	Year 1 CY2027	Year 2 CY2028
Administrator (FMC Clinic Manager)	1.00	1.00
Registered Nurses (RNs)	3.00	3.00
Home Training Nurses (HTRNs)	1.00	1.00
Technicians (PCT)	7.00	7.00
Dietician	1.00	1.00
Social Worker	1.00	1.00
Maintenance	1.00	1.00
Administration/Business Office	1.00	1.00
Other (FMC Director of Operations)	0.09	0.09
Other (FMC Chief Technician)	0.09	0.09
Other (FMC In-Service)	0.11	0.11
Total	16.29	16.29

Source: Section Q, Form H Staffing

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.4. In Section H, pages 52-53, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The facility is an existing facility, and the applicant bases its staffing on its historical experience providing dialysis services at the facility.
- The applicant has existing policies regarding recruitment, qualifications for staff, training, and continuing education.

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 all the reasons described 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.

FKC Regal Oaks proposes to add no more than two in-center dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 23 stations upon project completion

Ancillary and Support Services

In Section I, page 54, the applicant identifies the necessary ancillary and support services for the proposed services. On page 54-58, the applicant explains how each ancillary and support service is or will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available.

Coordination

In Section I, page 59, the applicant describes its existing and proposed relationships with other local health providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on its established relationships with other physicians and hospitals in the area and its agreements for lab services, hospital affiliation and transplant.

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 all the reasons described above.

- (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.

- (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

(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 ... persons [with disabilities], 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;

In Section L, page 66, the applicant provides the historical payor mix for CY2024 as shown in the table below.

FKC Regal Oaks						
Payment Source	In-Center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients
Self-Pay	2.8	5.9%				
Insurance*	6.6	13.8%				
Medicare*	30.2	62.9%				
Medicaid*	4.4	9.1%				
Other	4.0	8.4%				
Total	48.0	100.0%				

* Including any managed care plans.

In Section L, page 68, the applicant provides the following population comparison of the service area.

FKC Regal Oaks	Percentage of Total Patients Served (All modalities combined)	Percentage of the Population of the Service Area where the Stations will be Located or Services Offered*
Female	45.1%	51.0%
Male	54.9%	49.0%
Unknown		
64 and Younger	52.9%	86.6%
65 and Older	47.1%	13.4%
American Indian	2.0%	0.8%
Asian	3.9%	9.4%
Black or African-American	68.6%	20.6%
Native Hawaiian or Pacific Islander	3.9%	0.1%
White or Caucasian	5.9%	66.3%
Other Race	15.7%	18.6%
Declined / Unavailable	-	-

Sources: BMA Internal Data, US Census Bureau

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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 ... persons [with disabilities] to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

In Section L, pages 69, the applicant states that during the 18 months immediately preceding the application deadline no patient civil rights access complaints have been filed against FKC Regal Oaks.

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

In Section L, page 69, 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 CY2028						
Payment Source	In-Center		HH		PD	
	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients
Self-Pay	4.3	5.9%				
Insurance*	10.0	13.8%	3.0	50.0%		
Medicare*	45.9	62.9%	3.0	50.0%	5.0	100.0%
Medicaid*	6.6	9.1%				
Other-VA	6.1	8.4%				
Total	73.1	100.00	6.0	100.0%	5.0	100.0%

*Including any managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 62.9 percent of in-center patients will be Medicare recipients, 9.1 percent of in-center services will be provided to Medicaid recipients.

On pages 69-70, 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 because it is based on the historical payor mix at FKC Regal Oaks

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.

In Section L, page 71, 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

FKC Regal Oaks proposes to add no more than two in-center dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 23 stations upon project completion

In Section M, page 73, 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. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following:

- The applicant provides a copy of a letter sent to Central Piedmont Community College offering the facility as a training site for nursing students.
- FKC Regal Oaks has offered the facility as a clinical learning site for nursing students from Central Piedmont Community College.

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 all the reasons described above.

- (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

FKC Regal Oaks proposes to add no more than two in-center dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 23 stations upon project completion

On page 113, the 2025 SMFP defines the service area for dialysis stations as “...*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” 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 Table 9A, pages 125-126 of the 2025 SMFP, there are 23 existing or approved dialysis facilities in Mecklenburg County, as shown in the following table:

Dialysis Facility	Certified Stations 12/31/2023	Number In-Center Patients 12/31/2023	Utilization
BMA Bettis Ford	43	87	50.58%
BMA Nations Ford	28	95	84.82%
BMA of East Charlotte	32	118	92.19%
BMA West Charlotte	29	77	66.38%
Brookshire Dialysis	20	46	57.50%
Charlotte Dialysis	33	98	74.24%
Charlotte East Dialysis	34	91	66.91%
DSI Charlotte Latrobe Dialysis	24	63	65.63%
DSI Glenwater Dialysis	42	92	54.76%
FMC Charlotte	48	85	44.27%
FMC Matthews	21	91	108.33%
FMC of North Charlotte	40	133	81.13%
Fresenius Kidney Care Charlotte	0	0	0.00%
Fresenius Kidney Care Huntersville	0	0	0.00%
Fresenius Kidney Care Mallard Creek	12	39	81.25%
Fresenius Kidney Care Regal Oaks	17	60	88.24%
Fresenius Kidney Care Southeast Mecklenburg	17	52	76.47%
Fresenius Medical Care Aldersgate	16	52	81.25%
Fresenius Medical Care Southwest Charlotte	26	71	68.27%
Huntersville Dialysis	27	78	72.22%
INS Victory Home (replacement for INS Charlotte)	7	0	0.00%
Mint Hill Dialysis	21	49	58.33%
North Charlotte Dialysis	33	83	62.88%
South Charlotte Dialysis	27	74	68.52%

Source: Table 9A in the 2025 SMFP.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 74, the applicant states:

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

Regarding the impact of the proposal on cost effectiveness, in Section N, page 75, the applicant states:

“The applicant is serving a significant number of dialysis patients residing in the area of the facility. Approval will allow the facility to continue serving patients who reside in the area. Consequently, these patients will have a shorter commute to and from dialysis treatment. This is an immediate and significantly positive impact on the patients of the area.”

See also Sections C, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 75, the applicant states:

“Quality of care is always at the forefront of Fresenius Medical care-related facilities. Quality of care is not negotiable. Fresenius Medical Care, parent organization for Fresenius Medical Care, parent organization for this facility, expects every facility to high quality care to every patient at every treatment.”

See also Sections B, C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 75, the applicant states:

“Fresenius related facilities in North Carolina have historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, [disability], age or any other grouping/category or basis for being an underserved person. Low income and medically underinsured persons will continue to have access to all services provided by Fresenius related facilities.”

See also Sections C and L of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant’s representations about how it will ensure the quality of the proposed services and the applicant’s record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant’s representations about access by medically underserved groups and the projected payor mix.

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 based on all the reasons described 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

FKC Regal Oaks proposes to add no more than two in-center dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 23 in-center stations upon project completion

On Form O, pages 107-110, 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 133 existing or approved kidney disease treatment facilities located in North Carolina.

In Section O, page 8, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents resulting in an Immediate Jeopardy violation that occurred in any of these facilities. After reviewing and considering information provided by the applicant and considering the quality of care provided at all 133 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.

G.S. 131E-183 (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 kidney disease treatment center or dialysis facility shall document the need for at least 10 dialysis stations based on utilization of 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the facility. An applicant may document the need for less than 10 stations if the application is submitted in response to an adjusted need determination in the State Medical Facilities Plan for less than 10 stations.

-NA- FKC Regal Oaks is an existing facility. Therefore, this Rule is not applicable to this review.

(a) An applicant proposing to increase the number of dialysis stations in:

- (1) an existing dialysis facility; or*
- (2) a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need; shall document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the additional stations.*

-C- In Section C, page 37, and on Form C in Section Q, the applicant projects to serve 66.8 patients on 23 stations, or a rate of 2.9 in-center patients per station per week (66.8 patients / 23 stations = 2.9), by 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 proposing to establish a new dialysis facility dedicated to home hemodialysis or peritoneal dialysis training shall document the need for the total number of home hemodialysis stations in the facility based on training six home hemodialysis patients per station per year as of the end of the first full fiscal year of operation following certification of the facility.

-NA- The applicant does not propose to establish a new dialysis facility dedicated to home hemodialysis or peritoneal dialysis training. Therefore, this Rule does not apply.

(d) An applicant proposing to increase the number of home hemodialysis stations in a dialysis facility dedicated to home hemodialysis or peritoneal dialysis training shall document the need for the total number of home hemodialysis stations in the facility based on training six home hemodialysis patients per station per year as of the end of the first full fiscal year of operation following certification of the additional stations.

-NA- The applicant does not propose to increase the number of home hemodialysis stations. Therefore, this Rule does not apply.

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

- C- In Section C, pages 25-32, and in the Form C Utilization subsection of Section Q, the applicant provides the assumptions and methodology it used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.