

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: August 23, 2023

Findings Date: August 23, 2023

Project Analyst: Crystal Kearney

Co-Signer: Mike McKillip

Project ID #: E-12410-23

Facility: Fresenius Kidney Care Newton

FID #: 160340

County: Catawba

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

Project: Add no more than 2 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 17 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

The applicant, Bio-Medical Applications of North Carolina, Inc. (hereinafter referred to as “the applicant” or “FKC Newton”), proposes to add no more than 2 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 17 stations upon project completion.

Need Determination (Condition 2)

Chapter 9 of the 2023 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, page 131, the county need methodology shows there is not a county need determination for additional dialysis stations in Catawba County.

However, the applicant is eligible to apply for additional stations in an existing facility pursuant to Condition 2 of the facility need methodology in the 2023 SMFP, if the utilization rate for the facility as reported in the 2023 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 80% or 3.2 patients per station per week, based on 48 in-center dialysis patients and 15 certified dialysis stations (48 patients/15 stations = 3.2; $3.2 / 4 = 80.00\%$).

As shown in Table 9D, based on the facility need methodology for dialysis stations, the potential number of stations needed is up to 14 additional stations; thus, the applicant is eligible to apply to add up to 14 stations during the 2023 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than 2 new stations to the facility, which is less than the 2023 calculated facility need determination for up to 14 stations; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

Policies

There is one policy in the 2023 SMFP that is applicable to this review, Policy GEN-3: *Basic Principles*.

Policy *GEN-3*, page 30 of the 2023 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 21; Section N, page 74-75; Section O, pages 77-80; 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, page 22; Section C, page 31; Section L, pages 67-72; Section N, page 75; 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 22-23; Section F, pages 43-48; Section N, page 75; 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 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 2023 SMFP.
- The applicant adequately demonstrates how FKC Newton's projected volumes incorporate the concepts of safety and quality, equitable access, and maximum value for resources expended in meeting the facility need and is consistent with Policy GEN-3.

- (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 Newton proposes to add no more than 2 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 17 stations upon project completion.

Patient Origin

On page 113, the 2023 SMFP defines the service area for dialysis stations as "*the service area is the county in which the dialysis station is located*". Thus, the service area for this facility

consists of Catawba County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates historical and projected patient origin.

County	FKC Newton Patient Origin			
	Historical Last Full FY CY 2022		Projected 2 nd Full FY CY 2026	
	# of In-Center Patients	% of Total	# of In-Center Patients	% of Total
Catawba	34.0	68.0%	36.4	64.1%
Gaston	1.0	2.0%	1.0	1.8%
Lincoln	15.0	30.0%	19.4	34.1%
Total	50.0	100.0%	56.7	100.0%

Source: Section C, pages 25 - 26

The applicant does not propose to offer home hemodialysis or peritoneal dialysis training or support services.

In Section C, page 26-28, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s patient origin projections are reasonable and adequately supported because they are based the historical (CY2022) patient origin for the facility.

Analysis of Need

In Section C, pages 28-30, 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 population to be served as 55.0 in-center dialysis patients dialyzing with the facility as of the end of the first Operating Year of the project. This equates a utilization rate of 80.79%, or 3.23 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 2023 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 projected growth in the patient population.

Projected Utilization

In Section C, page 29, and Section Q, page 85, the applicant provides projected utilization, as illustrated in the following table.

FKC Newton	In-Center patients
Begin with the Catawba County patient population as of December 31, 2022.	34
Project the Catawba County patient population forward for one year to December 31, 2023, using the Catawba County Five-Year AACR.	$34.0 \times 1.017 = 34.6$
Begin with the Lincoln County patient population as of December 31, 2022	15.0
Project the Lincoln County patient population forward for one year to December 31, 2023, using the Lincoln County Five-Year AACR.	$15.0 \times 1.066 = 16.0$
Add one patient from other counties. This is the projected ending census for Interim Year 1.	$34.6 + 16.0 + 1.0 = 51.6$
Project the Catawba County patient population forward for one year to December 31, 2024, using the Lincoln County Five-Year AACR.	$34.6 \times 1.017 = 35.2$
Project the Lincoln County patient population forward for one year to December 31, 2024, using the Catawba County Five-Year AACR.	$16.0 \times 1.066 = 17.0$
Add the one patient from other counties. This is the projected ending census for Interim Year 2.	$35.2 \times 17.0 + 1.0 = 53.2$
Project the Catawba County patient population forward for one year to December 31, 2025, using the Catawba County 5-Year AACR.	$35.2 \times 1.017 = 35.8$
Project the Lincoln County patient population forward for one year to December 31, 2025, using the Catawba County 5-Year AACR.	$17.0 \times 1.066 = 18.2$
Add the one patient from other counties. This is the projected ending census for Operating Year 1.	$35.8 + 18.2 + 1.0 = 55.0$
Project the Catawba County patient population forward for one year to December 31, 2026, using the Catawba County 5-Year AACR.	$35.8 \times 1.017 = 36.4$
Project the Lincoln County patient population forward one year to December 31, 2026, using the Lincoln County 5-Year AACR.	$18.2 \times 1.066 = 19.4$
Add the one patient from other counties. This is the projected ending census for Operating Year 2.	$36.4 \times 19.4 + 1.0 = 56.7$

In Section C, pages 27-28 and Section Q, pages 85-86, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The 2023 SMFP, Table 9D indicates that FKC Newton qualifies to apply for up to 14 additional dialysis stations pursuant to Condition 2 of the Facility Need Methodology. This is an application for two additional dialysis stations.
- The applicant begins its projections of the future patient population to be served, with the facility census as of December 31, 2022. This information was reported on the 2022 ESRD Data Collection Form submitted to DHSR Planning in February 2023.
- The applicant projects growth of the Catawba County patient population using the Catawba County Five Year Annual Change Rate (5-Year AACR) of 1.7% as published in the 2023 SMFP.
- As of December 31, 2022, the facility was serving 15 in-center patients or 30% of patients residing in Lincoln County. Because a significant portion of the facility census resides in Lincoln County, the applicant projects growth of the Lincoln County segment of the population using the Lincoln County Five Year Average Annual Change Rate of 6.6%, as published in the 2023 SMFP.
- The facility was also serving one in-center patient residing in Gaston County. The patient is assumed to continue dialysis with the facility; however, the applicant does not project any growth for this segment of the patient population. This patient will be added to projections of future patient populations at appropriate points in time.
- The new stations are projected to be certified as of December 31, 2024.
 Operating Year 1 is the period from January 1-December 31, 2025
 Operating Year 2 is the period from January 1 – December 31, 2026

Summary: Based upon these calculations, FKC Newton projects to serve the following number of patients for the Operating Years 1 and 2.

	Operating Year 1	Operating Year 2
In-center	54.9	56.7

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

- OY1: 3.24 patients per station per week or 81% (55 patients /17 stations = 3.24; 3.24/4 = 0.81 or 81%)
- OY2: 3.35 patients per station per week or 83.75% (57 patients/17 stations = 3.35; 3.35/4 = .8375 or 83.75%).

The projected utilization of 3.24 patients per week at the end of OY1 exceeds the minimum standard of 2.8 in-center patients per station per week required by 10A NCAC 14C.2203(b).

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

- FKC Newton bases the projections of the future patient population to be served, based on the facility census as of December 31, 2022.

- FKC Newton projects growth of the Catawba County patient population using the Catawba County Five Year Average Annual Change Rate (5-Year AACR) of 1.7% as published in the 2023 SMFP.
- FKC Newton projects growth of the Lincoln County patient population using the Catawba County Five Year Average Annual Change Rate (5-Year AACR) of 6.6% as published in the 2023 SMFP.
- Projected utilization at the end of OY1 exceeds the minimum of 2.8 patients per station per week required by 10A NCAC 14C .2203(b).

Access to Medically Underserved Groups

In Section C, page 31, 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, 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.”

The applicant provides the estimated percentage during the second full fiscal year for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low-income persons	70.0%
Racial and ethnic minorities	48.0%
Women	46.0%
Person with disabilities	40.0%
Persons 65 and older	34.0%
Medicare beneficiaries	32.0%
Medicaid recipients	70.0%

Source: Section C, page 32.

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.

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 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 Newton proposes to add no more than 2 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 17 dialysis stations upon project completion.

In Section E, page 41, 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:

- The applicant could have chosen not to file for additional stations at FKC Newton. Failure to apply for additional stations at FKC Newton would ultimately result in higher utilization rates. The applicant has demonstrated that the projected utilization for the end of Operating Year 1 is 3.23 patients per station; the projected utilization for the end of Operating Year is 3.34 patients per station.
- The applicant could have chosen to file for less than two additional stations. An application for fewer than two stations would have the same effect as not applying: higher utilization rates as the facility patient census increases. This is not the most effective alternative. If FKC Newton had chosen to not apply for additional stations, utilization on 15 dialysis stations would be projected to be 3.66 patients per station at the end of Operating 1, and 3.78 patients per year at the end of Operating Year 2. Failure to apply for additional stations, utilization rates, potentially interrupts patient admissions to the facility and is the least effective alternative.
- An application for more than two stations is not cost effective. The facility does not have the physical space for more than 17 dialysis stations. Even though the facility qualifies to apply for as many as 14 stations, there is no room for more than two additional dialysis stations.

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 Applications 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 2023 SMFP, the certificate holder shall develop no more than two additional dialysis stations for a total of no more than 17 stations at FKC Newton.**
 - 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 on February 1, 2024.**
 - 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

The applicant proposes to add no more than 2 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 17 dialysis stations upon project completion.

Capital and Working Capital Costs

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

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

Source: Form F1.a, page 88 of the application.

In Section Q, page 89, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the applicant's experience with similar projects.

On page 45, the applicant states that there will be no start-up or initial operating expenses associated with the proposed project because FKC Newton is an existing facility.

Availability of Funds

In Section F, page 44, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	Bio-Medical Applications of North Carolina, Inc.	Total
Loans	\$	\$
Accumulated reserves or OE *	\$7,500	\$7,500
Bonds	\$	\$
Other (Specify)	\$	\$
Total Financing	\$	\$

* OE = Owner's Equity

Exhibit F-2 contains a letter dated June 17, 2023, from the Senior Vice President and Treasurer of Fresenius Medical Care Holdings, Inc., the parent company of the applicant, authorizing the use of accumulated reserves for the capital needs of the project. The letter in Exhibit F-2 also states that the 2021 Consolidated Balance Sheet reflects more than \$939 million in cash, and total assets exceeding \$27.2 billion.

The applicant adequately demonstrates the availability of sufficient funds for the capital and working 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.

FKC Newton	1st FFY CY 2025	2nd FFY CY 2026
Total Treatments (Form C)	8,003	8,264
Total Gross Revenues (Charges)	\$50,345,241	\$51,988,593
Total Net Revenue	\$2,338,310	\$2,414,636
Average Net Revenue per Treatment	\$292	\$292
Total Operating Expenses (Costs)	\$2,238,130	\$2,283,996
Average Operating Expense per Treatment	\$283	\$276
Net Income	\$100,180	\$130,640

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q. The applicant adequately demonstrate that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant provides reasonable assumptions in determining revenue and operating expenses in preparation of Form F.2, F.3, and F.4.
- 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 proposals and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.
- (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 no more than 2 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 17 dialysis stations upon project completion.

The 2023 SMFP, page 113, defines the service area for dialysis stations as *“the service area is the county in which the dialysis station is located.”* Thus, the service area for this facility consists of Catawba County. Facilities may also serve residents of counties not included in their service area.

According to Table 9A of the 2023 SMFP, there are 5 existing or approved dialysis facilities in Catawba County. Information of the Catawba County dialysis facilities, from Table 9A of the 2023 SMFP, is provided below:

Facility Name	Certified Stations as of 12/31/2021	# IC Patients as of 12/31/2021	Utilization by Percent as of 12/31/2021
Catawba County Dialysis	21	39	46.43%
FMC Dialysis Services of Hickory	33	95	71.97%
FMC of Catawba Valley	25	89	89.00%
FKC Newton	15	48	80.00%
FKC North Catawba*	0	0	0.00%

Source: Table 9A, Chapter 9, 2023 SMFP.

*New facility currently under development.

In Section G, page 50-51, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Catawba County. The applicant states:

“Given the utilization and growth of the facility, BMA does not believe adding two stations will duplicate any services. Rather, the additional stations will ensure continued adequate access to dialysis care for the patient population of the area. Further, the overall utilization for facilities in Catawba County was 2.85 patients per station or 71.28%, as of December 31, 2022, and the overall utilization for all operational BMA facilities in Catawba County was 3.07 patients per station or 76.71% as of December 31, 2022.”

The applicant adequately demonstrates that the proposal would 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 in Catawba County based on Condition 2 of the facility need determination in the 2023 SMFP.
- As shown in Table 9D on page 136 of the 2023 SMFP, based on the facility need methodology for dialysis stations, the potential number of stations needed at FKC Newton is up to fourteen additional stations; thus, the applicant is eligible to apply to add up to

fourteen stations during the 2023 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

- The applicant adequately demonstrates that the proposal dialysis stations are needed in addition to the existing and approved dialysis stations in Catawba County.

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 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

The applicant proposes to add no more than 2 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 17 dialysis stations upon projected completion.

In Section Q, Form H, pages 98-99, the applicant provides current and projected full-time equivalent (FTE) positions for FKC Newton facility, as summarized in the following table:

Position	Current FTE Staff	Projected FTE Staff	Projected FTE Staff
	As of 6/16/23	1 st Full Fiscal Year CY 2025	2 nd Full Fiscal Year CY 2026
Administrator (FMC Clinic Manager)	1.00	1.00	1.00
Registered Nurses (RNs)	1.75	1.75	1.75
Technicians (PCT)	6.00	6.00	6.00
Medical Records	0.25	0.50	0.50
Dietician	0.25	0.25	0.25
Social Worker	0.25	0.25	0.25
Maintenance	1.00	1.00	1.00
Administration/Clerical	0.25	0.50	0.50
Other (FMC Director of Operations)	0.60	0.60	0.60
Other (FMC) Chief Technician)	0.10	0.10	0.10
Other (FMC In-Service)	0.10	0.10	0.10
TOTAL	11.55	12.05	12.05

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, 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.

C

The applicant proposes to add no more than 2 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 17 dialysis 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 pages 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 care and social service 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. The applicant is not an HMO. 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 ... 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;

C

In Section L, page 66, the applicant provides the historical payor mix during CY 2022 for the proposed services, as shown in the table below.

FKC Newton Historical Payor Mix 01/01/2022-12/31/2022		
Payor Source	In-Center Dialysis	
	# of Patients	% of Total
Self-Pay	2.4	4.80%
Insurance*	2.2	4.31%
Medicare*	41.0	82.007%
Medicaid*	2.8	5.67%
Other	1.6	3.21%
Total	50.0	100.00%

*Including any managed care plans.

In Section L, page 68, the applicant provides the following comparison.

FKC Newton	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	46.0%	50.8%
Male	54.0%	49.2%
Unknown	0.0%	0.0%
64 and Younger	66.0%	81.5%
65 and Older	34.0%	18.5%
American Indian	0.0%	0.6%
Asian	2.0%	4.8%
Black or African American	32.0%	9.0%
Native Hawaiian or Pacific Islander	0.0%	0.2%
White or Caucasian	66.0%	83.2%
Other Race	0.0%	12.7%
Declined / Unavailable	0.0%	0.0%

*The percentages can be found online using the United States Census Bureau's QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 69, the applicant states:

“The facility is not obligated under any applicable federal regulations to provide uncompensated care, community service, or access by minorities and persons with disabilities.”

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

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 69, 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 Newton Projected Payor Mix 01/01/2026-12/31/2026		
Payor Source	In-Center Dialysis	
	# of Patients	% of Total
Self-Pay	2.7	4.80%
Insurance*	2.4	4.31%
Medicare*	46.5	82.00%
Medicaid*	3.2	5.67%
Other	1.8	3.21%
Total	56.7	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 4.80% of total services will be provided to self-pay patients, 82.00% to Medicare patients and 5.67% to Medicaid patients.

On page 70, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical (CY 2022) payor mix for the facility.

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 reasons stated above.

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

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

The applicant proposes to add no more than 2 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 17 dialysis 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 based on the following:

- FKC Newton has a history of allowing health-related education and training programs visit the facility to observe the operation of the unit while patients receive treatment.
- The applicant provides a copy of a letter sent to Catawba Valley Community College encouraging the school to include FKC Newton facility in their clinical rotations for nursing students.

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

The applicant proposes to add no more than 2 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 17 dialysis stations upon project completion.

On page 113, the 2023 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located.*” Thus, the service area for this facility consists of Catawba County. Facilities may also serve residents of counties not included in their service area.

According to Table 9A of the 2023 SMFP, there are 5 existing or approved dialysis facilities in Catawba County. Information of the Catawba County dialysis facilities, from Table 9A of the 2023 SMFP, is provided below:

Facility Name	Certified Stations as of 12/31/2021	# IC Patients as of 12/31/2021	Utilization by Percent as of 12/31/2021
Catawba County Dialysis	21	39	46.43%
FMC Dialysis Services of Hickory	33	95	71.97%
FMC of Catawba Valley	25	89	89.00%
FKC Newton	15	48	80.00%
FKC North Catawba*	0	0	0.00%

Source: Table 9A, Chapter 9, 2023 SMFP.

*New facility currently under development.

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 any effect on the competitive climate in Catawba County. ... The SMFP reports there are currently four operational and one CON approved dialysis facilities with in-center dialysis stations within Catawba County. Four of these facilities will be operated by Fresenius Medical Care. With this application, the applicant seeks the opportunity to continue providing dialysis care and treatment to the patients of the area who have expressed their desire to receive dialysis care and treatment at FKC Newton.”

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

“Approval of this application 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 to the patients of the area.”

See also Sections B, 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 in the forefront at Fresenius Medical Care related facilities...Fresenius Medical Care, parent organization for this facility, expects every facility to provide 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:

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

See also Sections B, L and C 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.
- 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 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

In Section Q, pages 102- 106, the applicant identifies the kidney disease treatment facilities located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 132 of this type of facility located in North Carolina.

In Section O, page 80, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to immediate jeopardy has not occurred in any of these facilities. After reviewing and considering information provided by the applicant and considering the quality of care provided at all 132 facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

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.

10A 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 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, 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 Newton is an existing facility. The applicant does not propose to establish a new kidney disease treatment center or dialysis facility. Therefore, this performance standard is not applicable to this review.

(b) 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 27 - 28 and Section Q, page 85-86, the applicant projects that FKC Newton will serve 55 in-center patients on 17 stations, or a rate of 3.24 in-center 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 27-28, and Section Q, pages 85-86, 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.