

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: May 7, 2025

Findings Date: May 7, 2025

Project Analyst: Tanya M. Saporito

Co-Signer: Gloria C. Hale

Project ID #: M-12620-25

Facility: Fresenius Kidney Care Rockfish

FID #: 170017

County: Cumberland

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

Project: Add no more than 9 in-center dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 25 in-center stations upon completion of this project and Project ID# M-12586-25 (relocate 9 stations)

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 nine dialysis stations to Fresenius Kidney Care Rockfish (“FKC Rockfish”) pursuant to Condition 2 of the facility need methodology for a total of no more than 25 stations upon completion of this project and Project ID #M-12586-25 (relocate nine stations).

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 the county need methodology summarized in Table 9C on page 136 of

the 2025 SMFP, there is not a county need determination for additional dialysis stations anywhere in the state.

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 or greater, as stated in Condition 2.a. The utilization rate reported for the facility on page 121 of the 2025 SMFP is 88.0% or 3.5 patients per station per week, based on 88 in-center dialysis patients and 25 certified dialysis stations ($88 \text{ patients} / 25 \text{ stations} = 3.52$, $3.52 / 4 = 0.88$).

As shown in Table 9D, on page 137 of the 2025 SMFP, based on the facility need methodology for dialysis stations, the potential number of stations needed is up to nine additional stations; thus, the applicant is eligible to apply to add up to nine stations during the 2025 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than nine new stations to the facility, which is consistent with the 2025 SMFP calculated facility need determination for up to nine 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: Access to Culturally Competent Healthcare*.

Policy GEN-5, pages 30-31 of the 2025 SMFP, states:

“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.

CON applications will include the following:

The applicant shall, in its CON application, address each of the items enumerated below:

Item 1: Describe the demographics of the relevant service area with a specific focus on the medically underserved communities within that service area. These communities shall be described in terms including, but not limited to: age, gender, racial composition; ethnicity; languages spoken; disability; education; household income; geographic location and payor type.

Item 2: Describe strategies it will implement to provide culturally competent services to members of the medically underserved community described in Item 1.

Item 3: Document how the strategies described in Item 2 reflect cultural competence.

Item 4: Provide support (e.g., best-practice methodologies, evidence-based studies with similar communities) that the strategies described in Items 2 – 3 are reasonable pathways for reducing health disparities, increasing health equity and improving the health outcomes to the medically underserved communities within the relevant service area.

Item 5: Describe how the applicant will measure and periodically assess increased equitable access to healthcare services and reduction in health disparities in underserved communities.”

Policy GEN-5. In Section B, pages 21-24, the applicant explains why it believes the application is conforming to Policy GEN-5.

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 2025 SMFP.
- The applicant adequately documents how the project will provide culturally competent dialysis care that integrates principles to increase health equity and reduce health disparities in underserved communities.

(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

BMA proposes to add no more than nine dialysis stations to FKC Rockfish pursuant to Condition 2 of the facility need methodology for a total of no more than 25 dialysis stations upon completion of this project and Project ID# M-12586-25 (relocate 9 stations).

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

In Section C, page 25, the applicant provides historical utilization for FKC Rockfish for the last full year of operation, calendar year (CY) 2024, as illustrated in the following table:

FKC ROCKFISH HISTORICAL PATIENT ORIGIN CY 2024		
COUNTY	# OF PATIENTS	% OF TOTAL
Cumberland	81.0	85.3%
Hoke	12.0	12.6%
Lincoln	1.0	1.1%
Robeson	1.0	1.1%
Total	95.0	100.0%

In Section C, page 26, the applicant provides projected utilization for FKC Rockfish for the second full year of operation, calendar year (CY) 2029, as illustrated in the following table:

FKC ROCKFISH PROJECTED PATIENT ORIGIN CY 2029		
COUNTY	# OF PATIENTS	% OF TOTAL
Cumberland	77.0	86.5%
Hoke	11.0	12.4%
Robeson	1.0	1.1%
Total	89.0	100.0%

In Section C, pages 26-28, the applicant provides the assumptions and methodology used to project its patient origin, summarized as follows:

- The applicant relies on historical patient origin to project patient origin for the facility following the addition of nine dialysis stations.
- The applicant accounts for those patients who dialyze at FKC Rockfish and who reside in a county other than Cumberland County.
- The applicant subtracts from the projected patient census those patients who signed a letter indicating an intent to transfer their care to the new FKC Spring Lake dialysis facility pursuant to Project ID #M-12586-25 (Develop a new dialysis facility by relocating no more than 6 dialysis stations from FMC Services of West Fayetteville and no more than 9 dialysis stations from FKC Rockfish for a total of no more than 15 stations upon project completion).

The applicant's assumptions are reasonable and adequately supported based on the information in the application and for all the reasons described above.

Analysis of Need

In Section C, page 29, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, summarized as follows:

- The applicant proposes to develop nine new in-center dialysis stations in response to the facility need determination, as a back-fill for those stations to be relocated pursuant to Project ID #M-12586-25.
- The applicant states patients with End Stage Renal Disease (ESRD) require regular and consistent dialysis treatments to sustain life. Those treatments are typically three days per week on a continual basis. The need the dialysis patient population has for these treatments is thus a function of individual patient need.
- The applicant projects that 87.8 in-center dialysis patients will be served by the facility by the end of the first Operating Year. This equates to a utilization rate of 87.8%, or 3.512 patients per station per week 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 the need methodology found in Criterion (1) is incorporated herein by reference.

- The applicant adequately demonstrates need based on the facility's experience serving the dialysis patient population and projected growth of that population.

Projected Utilization

In Section C, pages 27-28 and Section Q, pages 79-80, the applicant provides interim and projected utilization for FKC Rockfish, as illustrated in the following table:

FKC ROCKFISH PROJECTED UTILIZATION IN-CENTER PATIENTS	
Begin with the Cumberland County patient population as of December 31, 2024.	81.0
Project the Cumberland County patient population forward for one year to December 31, 2025, using 1.5% growth rate based on the Cumberland County Five Year AACR.	$81.0 \times 1.015 = 82.2$
Add patients from outside Cumberland County (12 from Hoke County, one from Robeson County). This is projected ending census for Interim Year one.	$82.2 + 13.0 = 95.2$
Project the Cumberland County patient population forward for one year to December 31, 2026, using 1.5% growth rate based on the Cumberland County Five Year AACR.	$82.2 \times 1.015 = 83.4$
Add patients from outside Cumberland County (12 from Hoke County, one from Robeson County). This is projected ending census for Interim Year two.	$83.4 + 13.0 = 96.4$
Project the Cumberland County patient population forward for one year to December 31, 2027, using 1.5% growth rate based on the Cumberland County Five Year AACR.	$83.4 \times 1.015 = 84.7$
Subtract the Cumberland County patients projected to transfer their care to FKC Spring Lake on December 31, 2027 (Project ID #M-12586-25).	$84.7 - 10.0 = 74.7$
Subtract the Hoke County patients projected to transfer their care to FKC Spring Lake on December 31, 2027 (Project ID #M-12586-25).	$12.0 - 1.0 = 11.0$
Add patients from outside Cumberland County (11 from Hoke County, one from Robeson County). This is projected ending census for Interim Year three.	$74.7 + 12.0 = 86.7$
Project the Cumberland County patient population forward for one year to December 31, 2028, using 1.5% growth rate based on the Cumberland County Five Year AACR.	$74.7 \times 1.015 = 75.8$
Add patients from outside Cumberland County (11 from Hoke County, one from Robeson County). This is projected ending census for operating year one.	$75.8 + 12.0 = 87.8$
Project the Cumberland County patient population forward for one year to December 31, 2029, using 1.5% growth rate based on the Cumberland County Five Year AACR.	$75.8 \times 1.015 = 77.0$
Add patients from outside Cumberland County (11 from Hoke County, one from Robeson County). This is projected ending census for operating year two.	$77.0 + 12.0 = 89.0$

In Section C, pages 26-29 and Section Q, pages 79-80, the applicant provides the assumptions used to project utilization, summarized as follows:

- The applicant states the 2025 SMFP indicates that FKC Rockfish is qualified to apply for up to nine additional dialysis stations pursuant to Condition 2 of the Facility Need Methodology. The applicant proposes to add nine stations to FKC Rockfish.
- The applicant states the stations proposed in this application will be a backfill of nine stations relocated from FKC Rockfish pursuant to Project ID #M-12586-25.

- The applicant begins its projections with the facility census as of December 31, 2024.
- The applicant projects growth in Cumberland County patients using the Cumberland County Five Year Average Annual Change Rate (AACR) of 1.5% as published in the 2025 SMFP.
- The applicant states that, as of December 31, 2024, the facility served a total of 14 in-center patients residing in the following counties: 12 patients in Hoke County and one patient each in Lincoln and Robeson counties. The applicant states Hoke and Robeson counties are contiguous to Cumberland County. The applicant does not project growth in that patient population but adds those patients to its projections at appropriate points in time. The one patient who resides in Lincoln County is assumed to be a transient patient and thus will not be carried forward in the applicant's projections.
- The applicant was approved, pursuant to Project ID #M-12586-25 to relocate nine in-center dialysis stations to a new facility. The applicant therefore subtracts the number of patients who indicated an intent to transfer their care to that facility from the projections in this application.
- The applicant states operating year one is CY 2028 and operating year two is CY 2029.

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

- The applicant projects future utilization based on historical utilization.
- The applicant's proposal to add nine dialysis stations will replace those stations approved to be relocated pursuant to Project ID #M-12586-25 and will continue to meet the need of the projected patient population.
- 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:

"The applicant and its parent organization, Fresenius Medical Care, has a long history of providing dialysis services to the underserved populations of North Carolina. ... Fresenius Medical Care operates more than 100 dialysis facilities across North Carolina. 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."

In Section C, page 32 the applicant provides the estimated percentage for each medically underserved group, as shown in the following table:

MEDICALLY UNDERSERVED GROUPS	PERCENTAGE OF TOTAL PATIENTS
Low-income persons	39.8%
Racial and ethnic minorities	86.7%
Women	49.4%
Persons with disabilities	15.7%
Persons 65 and older	42.2%
Medicare beneficiaries	34.9%
Medicaid recipients	37.3%

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 because FKC Rockfish is an existing dialysis facility that currently provides services to underserved groups. The applicant states FKC Rockfish will continue to provide access to these groups and all persons in need of dialysis services.

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.

- (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 service. Therefore, Criterion (3a) is not applicable to this review.

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

The applicant proposes to add no more than nine dialysis stations to FKC Rockfish pursuant to Condition 2 of the facility need methodology for a total of no more than 25 dialysis stations upon completion of this project and Project ID# M-12586-25 (relocate 9 stations).

In Section E, page 39, the applicant states it did not consider an alternative to the application as submitted. The applicant states:

“Failure to apply for additional stations at FKC Rockfish would ultimately result in higher utilization rates. ...

If the applicant had chosen not to apply for additional stations, utilization on 16 dialysis stations would be projected to be 5.49 patients per station at the end of Operating Year 1, and 5.56 patients [per station] at the end of Operating Year 2.”

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

- The applicant’s proposal is in response to a facility need pursuant to Condition 2 of the facility need methodology, as reported in the 2025 SMFP.
- The applicant provides reasonable information to explain why it proposes to back-fill nine stations that were relocated to another facility pursuant to Project ID #M-12586-25.
- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

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 2025 SMFP, the certificate holder shall develop no more than nine additional dialysis stations for a total of no more than 25 dialysis stations at Fresenius Kidney Care Rockfish upon project completion.**
- 3. The certificate holder shall develop and implement strategies to provide culturally competent services to members of its defined medically underserved community that are consistent with representations made in the certificate of need application.**

4. 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 November 1, 2025.

5. 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 nine dialysis stations to FKC Rockfish pursuant to Condition 2 of the facility need methodology for a total of no more than 25 dialysis stations upon completion of this project and Project ID# M-12586-25 (relocate 9 stations).

Capital and Working Capital Costs

On Form F.1a, in Section Q, page 82, the applicant states this application is a *“backfill of nine existing stations, therefore, the applicant does not propose any capital cost to complete this project.”*

In Section F, page 42, the applicant states that there will be no start-up costs or initial operating expenses because this is an existing operational facility.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following project completion. In Form F.2, the applicant projects that revenues will exceed operating expenses in the first two full fiscal years following project completion, CYs 2028-2029, as shown in the following table:

	1 ST OY CY 2028	2 ND OY CY 2029
Total # of Treatments (Form C.2)	12,915	13,082
Gross Revenue	\$81,245,178	\$82,296,263
Net Revenue	\$4,082,947	\$4,135,769
Avg. Net Revenue/Treatment	\$316	\$316
Operating Costs	\$3,333,728	\$3,379,972
Avg. Operating Cost/Treatment	\$258	\$258
Net Income	\$749,219	\$755,797

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 based on the information contained in the application and exhibits and based on the following:

- 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 revenues and operating expenses.
- (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 nine dialysis stations to FKC Rockfish pursuant to Condition 2 of the facility need methodology for a total of no more than 25 dialysis stations upon completion of this project and Project ID# M-12586-25 (relocate 9 stations).

On page 113, the 2025 SMFP defines the service area for dialysis stations as *“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 Cumberland County. Facilities may also serve residents of counties not included in their service area.

Table 9A on page 121 of the 2025 SMFP shows six existing or approved dialysis facilities in Cumberland County as of December 31, 2023. The following table illustrates Cumberland County dialysis facilities and utilization as shown in Table 9A:

FACILITY	# STATIONS	# PATIENTS	% UTILIZATION
Fayetteville Kidney Center	57	164	71.93%
FMC Dialysis Services North Ramsey	54	128	59.26%
FMC Dialysis Services South Ramsey	56	158	70.54%
FMC Services of West Fayetteville	40	137	85.63%
FKC Hope Mills	0	0	0.00%
FKC Rockfish	25	88	88.00%

*Fresenius Kidney Care Hope Mills is under development pursuant to Project ID #M-12129-21.

In Section G, pages 46-47, the applicant explains why it believes its proposal would not result in the necessary duplication of existing or approved dialysis services in Cumberland County. The applicant states:

“This application proposes to develop nine additional dialysis stations at an existing facility pursuant to Condition 2 of the Facility Need Methodology in the 2025 SMFP. The stations proposed in this application will be a backfill of nine stations at FKC Rockfish pursuant to Project ID #M-12586-25(relocate 9 stations).

...

BMA does not believe adding nine stations to an existing facility to backfill stations requested for relocation to develop a new facility will duplicate any services because approval of this application will net the facility with the same number of stations that they are already certified for. This application will merely ensure continued adequate access to dialysis care for the patient population in Cumberland County and the FKC Rockfish facility.”

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:

- Pursuant to the facility need determination in the 2025 SFMP, there is a need for up to nine dialysis stations at FKC Rockfish.
- The applicant adequately demonstrates that the proposed backfill of stations previously approved to be relocated to a new facility is needed by the patients who dialyze at FKC Rockfish.

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

The applicant proposes to add no more than nine dialysis stations to FKC Rockfish pursuant to Condition 2 of the facility need methodology for a total of no more than 25 dialysis stations upon completion of this project and Project ID# M-12586-25 (relocate 9 stations).

In Section Q, Form H on page 93, the applicant projects full-time equivalent (FTE) staffing for the proposed dialysis stations, as illustrated in the following table.

POSITION	1 ST OY CY 2028	2 ND OY CY 2029
Administrator	1.00	1.00
Registered Nurses (RNs)	4.00	4.00
Technicians	8.00	8.00
Dietician	1.00	1.00
Social Worker	1.00	1.00
Maintenance	0.50	0.50
Administrative/Clerical	1.00	1.00
Other (FMC Dir. of Operations)	0.20	0.20
Other (FMC Chief Technician)	0.15	0.15
Other (FMC In-Service)	0.15	0.15
Total	20.00	20.00

Source: Section Q, Form H, page 93

The assumptions and methodology used to project staffing are provided following Form H 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 Q. In Section H, pages 48-49 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 applicant states projected staffing is based on what is necessary for dialysis facility operation.
- The applicant projects sufficient operating expenses for the staff proposed by the applicant.
- The applicant describes the required qualifications for staff, continuing education, and other training programs.

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 nine dialysis stations to FKC Rockfish pursuant to Condition 2 of the facility need methodology for a total of no more than 25 dialysis stations upon completion of this project and Project ID# M-12586-25 (relocate 9 stations).

Ancillary and Support Services

In Section I, page 50, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 50-54, 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 because it currently provides the necessary services as an existing, operational facility and states it will continue to do so.

Coordination

In Section I, page 55, the applicant describes its existing relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system because it has longstanding relationships with local health care and social service providers and has agreements in place with other ESRD-related service providers.

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. 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 proposes to add no more than nine dialysis stations to FKC Rockfish pursuant to Condition 2 of the facility need methodology for a total of no more than 25 dialysis stations upon completion of this project and Project ID# M-12586-25 (relocate 9 stations).

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 62, the applicant provides the historical payor mix during CY 2024 for FKC Rockfish, as shown in the following table:

FKC Rockfish Historical Payor Mix, CY 2024

PAYOR SOURCE	# OF PTS.	% OF TOTAL
Self-Pay	0.5	0.6%
Insurance*	3.8	4.0%
Medicare*	66.8	70.3%
Medicaid*	6.8	7.2%
Other^	17.1	18.0%
Total	95.0	100.00%

*Includes any managed care plans

^On page 63 the applicant states "other" includes all other reimbursement sources, including VA

In Section L, page 64, the applicant provides the following comparison.

FKC Rockfish		
	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	49.4%	52.6%
Male	50.6%	47.4%
Unknown		
64 and Younger	57.8%	71.2%
65 and Older	42.2%	28.8%
American Indian		1.0%
Asian	2.4%	0.5%
Black or African-American	75.9%	48.1%
Native Hawaiian or Pacific Islander	3.6%	
White or Caucasian	8.4%	48.0%
Other Race	9.6%	6.8%
Declined / Unavailable		

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

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 65, the applicant states it has no such obligation.

In Section L, page 65, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights equal access complaints have been filed against its facilities.

The Agency reviewed the:

- Application

- Exhibits to the application

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

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

C

In Section L, pages 65, the applicant projects the following payor mix during the second full fiscal year of operation following project completion, CY 2029, as illustrated in the following table:

FKC Rockfish Projected Payor Mix, Second Project Year

PAYOR SOURCE	# OF PTS.	% OF TOTAL
Self-Pay	0.5	0.6%
Insurance*	3.5	4.0%
Medicare*	62.6	70.3%
Medicaid*	6.4	7.2%
Other^	16.0	18.0%
Total	89.0	100.00%

*Includes any managed care plans

^On page 65 the applicant states "other" includes all other reimbursement sources, including VA

As shown in the table above, during the second full fiscal year of operation, the applicant projects 0.6% of services will be provided to self-pay patients, 70.3% to Medicare patients; and 7.2% to Medicaid patients.

On pages 65-66 the applicant provides the assumptions and methodology it uses to project payor mix during the second full fiscal year of operation following project completion. The projected payor mix is reasonable and adequately supported because it is based on the historical payor source data from 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.

- (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 67, 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 nine dialysis stations to FKC Rockfish pursuant to Condition 2 of the facility need methodology for a total of no more than 25 dialysis stations upon completion of this project and Project ID# M-12586-25 (relocate 9 stations).

In Section M, page 68, 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 a letter to Fayetteville Technical Community College encouraging the school to continue to include the dialysis 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 nine dialysis stations to FKC Rockfish pursuant to Condition 2 of the facility need methodology for a total of no more than 25 dialysis stations upon completion of this project and Project ID# M-12586-25 (relocate 9 stations).

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.” The applicant proposes to add stations to an existing dialysis facility in Cumberland County. Thus, the service area for this facility consists of Cumberland County. Facilities may also serve residents of counties not included in their service area.

Table 9A on page 121 of the 2025 SMFP shows six existing or approved dialysis facilities in Cumberland County as shown in the following table:

FACILITY	# STATIONS	# PATIENTS	% UTILIZATION
Fayetteville Kidney Center	57	164	71.93%
FMC Dialysis Services North Ramsey	54	128	59.26%
FMC Dialysis Services South Ramsey	56	158	70.54%
FMC Services of West Fayetteville	40	137	85.63%
FKC Hope Mills	0	0	0.00%
FKC Rockfish	25	88	88.00%

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 69, the applicant states:

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

Regarding the impact of the proposal on cost effectiveness, in Section N, page 70, the applicant states:

“This is a proposal to add nine dialysis stations to the FKC Rockfish facility. The applicant is serving a significant number of dialysis patients residing in the area of the facility. 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 on the patients of the area.”

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

Regarding the impact of the proposal on quality, in Section N, page 70, the applicant states:

“Quality care is not negotiable. Fresenius Medical Care, parent organization for this facility, expects every facility to provide high quality care to every patient at every treatment. Our organizational mission statement captures this sentiment very well:

‘We deliver superior care that improves the quality of life of every patient, every day, setting the standard by which others in the healthcare industry are judged.’”

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 70, 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.

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, handicap, age or any other grouping/category or basis for being an underserved person.”

See also Sections B, 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.
- 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

The applicant proposes to add no more than nine dialysis stations to FKC Rockfish pursuant to Condition 2 of the facility need methodology for a total of no more than 25 dialysis stations upon completion of this project and Project ID# M-12586-25 (relocate 9 stations).

In Section O, page 75, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to immediate jeopardy had not occurred in any of the Fresenius Medical Care related facilities in North Carolina. After reviewing and considering information provided by the applicant, 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 Rockfish is an existing facility. Therefore, this rule is not applicable to this review.
- (b) *An applicant proposing to increase the number of dialysis stations in:*
(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 34, and Section Q, page 80, the applicant projects that FKC Rockfish will serve 87.8 in-center patients on 25 stations, or a rate of 3.51 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 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 and does not plan to begin offering those services in this application. 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 dedicated to home hemodialysis or peritoneal dialysis training and does not plan to begin offering those services in this application. 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 26-29, and Section Q, pages 79-80, 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.