

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: February 26, 2024

Findings Date: February 26, 2024

Project Analyst: Tanya M. Saporito

Co-Signer: Mike McKillip

Project ID #: M-12462-23

Facility: FMC Anderson Creek

FID #: 110803

County: Harnett

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

Project: Add no more than one dialysis station 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

Bio-Medical Applications of North Carolina, Inc. (hereinafter referred to as “the applicant” or “BMA”), proposes to add no more than one 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 132, the county need methodology shows there is not a county need determination for additional dialysis stations in Harnett 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% or 3.0 patients per station per week, as stated in Condition 2.a. The utilization rate reported for the facility is 85.94% or 3.4 patients per station per week, based on 55 in-center dialysis patients and 16 certified dialysis stations [55 patients / 16 stations = 3.4; 3.4 / 4 = 0.8594].

As shown in Table 9D, page 136 of the 2023 SMFP, based on the facility need methodology for dialysis stations, the potential number of stations needed is up to three additional stations; thus, the applicant is eligible to apply to add up to three stations during the 2023 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than one new station to the facility, which is less than the 2023 calculated facility need determination for up to three 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 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, pages 22-23; Section C, page 33; Section L, pages 66-71; 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 N, pages 74-75; 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 FMC Anderson Creek'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

The applicant proposes to add no more than one dialysis station to FMC Anderson Creek pursuant to Condition 2 of the facility need methodology in the 2023 SMFP, 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 Harnett County. Facilities may also serve residents of counties not included in their service area.

The following table from Section C, page 25 illustrates historical patient origin for calendar year (CY) 2022 for FMC Anderson Creek:

FMC Anderson Creek, Historical Patient Origin, CY 2022

COUNTY	FMC ANDERSON CREEK LAST FULL FY (CY 2022)					
	# IN-CTR. PTS.	% OF TOTAL	# HHD PTS.	% OF TOTAL	# PD PTS.	% OF TOTAL
Harnett	30.0	55.6%	1.0	33.3%	6.0	66.7%
Cumberland	21.0	38.9%	1.0	33.3%	2.0	22.2%
Lee	3.0	5.6%	1.0	33.3%	1.0	11.1%
Total	54.0	100.0%	3.0	100.0%	9.0	100.0%

The following table from Section C, page 26 illustrates projected patient origin for operating year (OY) two, calendar CY 2026 for FMC Anderson Creek:

FMC Anderson Creek, Projected Patient Origin, CY 2026

COUNTY	FMC ANDERSON CREEK SECOND FULL OY (CY 2026)					
	# IN-CTR. PTS.	% OF TOTAL	# HHD PTS.	% OF TOTAL	# PD PTS.	% OF TOTAL
Harnett	31.5	54.7%	1.0	34.4%	6.3	67.7%
Cumberland	23.1	40.1%	1.0	32.8%	2.0	21.5%
Lee	3.0	5.2%	1.0	32.8%	1.0	10.8%
Total	57.6	100.0%	3.0	100.0%	9.3	100.0%

In Section C, page 26-29, 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 (CY 2022) patient origin for the facility.

Analysis of Need

In Section C, pages 30-31, 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 56.6 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 83.3%, or 3.33 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 of the current dialysis patient population.

Projected Utilization

In Section Q, page 83, the applicant provides the following table to illustrate projected utilization:

	LAST FULL FY (CY 2022)	INTERIM FULL FY (CY 2023)	INTERIM FULL FY (CY 2024)	1 ST FULL FY (CY 2025)	2 ND FULL FY (CY 2026)
In-Center Patients					
# Pts. Beginning of Year	55	54	55	56	57
# Pts. End of Year	54	55	56	57	58
Average # Pts. During the Year	55	54	55	56	57
# Treatments/Patient/Year	148	148	148	148	148
Total # Treatments	7,729	8,056	8,185	8,317	8,451
Home Hemodialysis Patients					
# Pts. Beginning of Year	2	3	3	3	3
# Pts. End of Year	3	3	3	3	3
Average # Pts. During the Year	3	3	3	3	3
# Treatments/Patient/Year	148	148	148	148	148
Total # Treatments	545	445	447	448	450
Peritoneal Dialysis Patients					
# Pts. Beginning of Year	9	9	9	9	9
# Pts. End of Year	9	9	9	9	9
Average # Pts. During the Year	9	9	9	9	9
# Treatments/Patient/Year	148	148	148	148	148
Total # Treatments	1,458	1,337	1,348	1,359	1,370
Total Patients					
# Pts. Beginning of Year	66	66	67	68	69
# Pts. End of Year	66	67	68	69	70
Average # Pts. During the Year	66	66	67	68	69
# Treatments/Patient/Year	148	148	148	148	148
Total # Treatments	9,732	9,838	9,980	10,124	10,271

In Section Q, pages 84-88, the applicant provides the assumptions and methodology used to project utilization, as summarized below.

In-Center Utilization

- Table 9D in the 2023 SMFP indicates that FMC Anderson Creek qualifies to apply for up to three additional dialysis stations pursuant to Condition 2 of the Facility Need Methodology. This is an application for one additional dialysis station.
- The applicant begins its projections with the facility census as of December 31, 2022 as reported on the 2022 ESRD Data Collection Form submitted to DHSR Planning in February 2023.
- The applicant projects growth of the Harnett County patient population using the Harnett County Five Year Annual Change Rate (5-Year AACR) of 1.2% as published in the 2023 SMFP.
- The applicant states as of December 31, 2022, the facility was serving 21 in-center patients from Cumberland County, which is contiguous to Harnett County. The applicant projects growth of the Cumberland County patient population using the Cumberland County Five Year AACR of 2.4% as published in the 2023 SMFP.
- The applicant states as of December 31, 2022, the facility was serving three in-center patients from Lee County, which is contiguous to Harnett County. The applicant projects these patients will continue to dialyze at FMC Anderson Creek but does not project growth of this patient population.

The following table from Section Q page 85 illustrates the projections:

Begin with Harnett County patient population as of 12/3/122	30.0
Project the Harnett County patient population forward to 12/21/22 using the Harnett County Five Year AACR	$30 \times 1.012 = 30.4$
Begin with Cumberland County patient population as of 12/31/22	21.0
Project the Cumberland County patient population forward to 12/31/23 using the Cumberland County Five Year AACR	$21.0 \times 1.024 = 21.5$
Add the patients from other counties. This is the projected census for Interim Year 1	$30.4 + 21.5 + 3.0 = 54.9$
Project the Harnett County patient population forward to 12/21/24 using the Harnett County Five Year AACR	$30.4 \times 1.012 = 30.7$
Project the Cumberland County patient population forward to 12/31/24 using the Cumberland County Five Year AACR	$21.5 \times 1.024 = 22.0$
Add the patients from other counties. This is the projected census for Interim Year 2	$30.7 + 22.0 + 3.0 = 55.7$
Project the Harnett County patient population forward to 12/21/25 using the Harnett County Five Year AACR	$30.7 \times 1.012 = 31.1$
Project the Cumberland County patient population forward to 12/31/25 using the Cumberland County Five Year AACR	$22.0 \times 1.024 = 22.5$
Add the patients from other counties. This is the projected census for Operating Year 1	$31.1 + 22.5 + 3.0 = 56.6$
Project the Harnett County patient population forward to 12/21/25 using the Harnett County Five Year AACR	$31.1 \times 1.012 = 31.5$
Project the Cumberland County patient population forward to 12/31/25 using the Cumberland County Five Year AACR	$22.5 \times 1.024 = 23.1$
Add the patients from other counties. This is the projected census for Operating Year 2	$31.5 + 23.1 + 3.0 = 57.6$

The projected utilization of 3.4 patients per station 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).

Home Dialysis Utilization

- The applicant begins its projections with the facility census as of December 31, 2022 as reported on the 2022 ESRD Data Collection Form submitted to DHSR Planning in February 2023.
- The applicant projects growth of the Harnett County patient population using the Harnett County Five Year Annual Change Rate (5-Year AACR) of 1.2% as published in the 2023 SMFP.
- The applicant states as of December 31, 2022, the facility was serving two home hemodialysis patients who reside in Cumberland and Lee counties, which are contiguous to Harnett County. The applicant states the patients who reside in Lee and Cumberland counties are projected to continue to dialyze at FMC Anderson Creek, but the applicant does not project growth in this patient population. See the table in Section Q pages 87-88 that illustrate home dialysis patient projections.

- The proposed 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.

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

- Utilization projections are based on historical patient census at the facility and the applicable Five Year AACR values for each county in the service area.
- The applicant’s proposal to add one dialysis station will meet the projected need for future patient populations at the facility.
- 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 33, 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 from page 33:

MEDICALLY UNDERSERVED GROUP	PERCENTAGE OF TOTAL PATIENTS
Low-income persons	25.4%
Racial and ethnic minorities	81.7%
Women	46.5%
Person with disabilities	16.9%
Persons 65 and older	35.2%
Medicare beneficiaries	77.5%
Medicaid recipients	25.4%

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.

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 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

The applicant proposes to add no more than one dialysis station to FMC Anderson Creek pursuant to Condition 2 of the facility need methodology in the 2023 SMFP, for a total of no more than 17 stations upon project completion.

In Section E, page 42, 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:

- Do not file for additional dialysis stations at FMC Anderson Creek – The applicant states that failure to apply for additional stations at FMC Anderson Creek would ultimately result in higher utilization rates, potentially interrupts patient admissions to the facility and is the least effective alternative.

- File for up to three additional dialysis stations – The applicant states the facility will not accommodate more than one additional dialysis station.

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

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible and supported information to explain why it believes the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 1. Bio-Medical 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 one additional in-center dialysis station at FMC Anderson Creek for a total of no more than 17 in-center stations upon project completion.**
- 3. Progress Reports**
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. The certificate holder shall complete all sections of the Progress Report form.**
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. The first progress report shall be due on September 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 one dialysis station to FMC Anderson Creek pursuant to Condition 2 of the facility need methodology in the 2023 SMFP, for a total of no more than 17 stations upon project completion.

Capital and Working Capital Costs

In Section F, Form F.1a, page 42, the applicant projects the total capital cost of the project, as shown in the table below.

Non-Medical Equipment	\$750
Furniture	\$3,000
Total	\$3,750

In Section Q, page 91, 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.

In Section F page 45, the applicant states that there will be no start-up or initial operating expenses associated with the proposed project because FMC Anderson Creek is an existing facility.

Availability of Funds

In Section F, page 43, the applicant states that the capital cost will be funded as shown in the table below.

SOURCE OF FINANCING	TOTAL
Loans	\$0
Accumulated reserves or OE *	\$3,750
Bonds	\$0
Other (Specify)	\$0
Total Financing	\$3,750

* OE = Owner's Equity

Exhibit F-2 contains a letter dated November 15, 2023, from the Vice President, Corporate Tax North America of Fresenius Medical Care Holdings, Inc., the parent company of the applicant, confirming the availability of and authorizing the use of sufficient accumulated reserves for the project capital cost. The letter in Exhibit F-2 also states that the 2022 Consolidated Balance Sheet reflects more than \$446 million in cash, and total assets exceeding \$25 billion.

The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project based on the representations in the application and 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 project completion. In Section Q, Form F.2 the applicant projects that operating expenses will exceed revenues in the first two full fiscal years following project completion, as shown in the following table:

FMC ANDERSON CREEK	1ST OY CY 2025	2ND OY CY 2026
Total In-Center Treatments (Form C)	10,124	10,271
Total Gross Revenues (Charges)	\$63,689,730	\$64,613,603
Total Net Revenue	\$3,614,331	\$3,663,967
Average Net Revenue per Treatment	\$357	\$357
Total Operating Expenses (Costs)	\$2,928,707	\$2,971,893
Average Operating Expense per Treatment	\$289	\$289
Net Income	\$685,624	\$692,074

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q, page 94. 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 one dialysis station to FMC Anderson Creek pursuant to Condition 2 of the facility need methodology in the 2023 SMFP, for a total of no more than 17 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 Harnett County. Facilities may also serve residents of counties not included in their service area.

The table below, taken from Table 9A on page 123 of the 2023 SMFP, lists the existing and approved facilities, certified station, and utilization of dialysis facilities in Harnett County as of December 31, 2021. There are four kidney disease treatment centers providing dialysis services in Harnett County.

HARNETT COUNTY DIALYSIS FACILITIES	PROVIDER	CERTIFIED STATIONS AS OF 12/31/21	# OF IC PATIENTS AS OF 12/31/21	% UTILIZATION AS OF 12/31/21
Dunn Kidney Center	BMA	35	100	71.43%
FMC Anderson Creek	BMA	16	55	85.94%
FMC Angier	BMA	12	24	50.00%
FMC Lillington	BMA	16	55	85.94%

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

“BMA is the only provider of dialysis services in Harnett County. This application is to add one dialysis station to an existing dialysis facility based upon the performance and demonstrated need at the FMC Anderson Creek facility. The need addressed by this applicant is not specific to Harnett County as a whole. The stations are needed by the patient population projected to be served by the 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:

- The applicant is the only provider of dialysis services in Harnett County.
- The applicant proposes to increase the number of dialysis stations at FMC Anderson Creek based on Condition 2 of the facility need determination in the 2023 SMFP.
- The applicant adequately demonstrates that the proposed dialysis station is needed in addition to the existing or approved dialysis stations in Harnett 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 one dialysis station to FMC Anderson Creek pursuant to Condition 2 of the facility need methodology in the 2023 SMFP, for a total of no more than 17 stations upon project completion.

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

FMC ANDERSON CREEK	1ST FULL FY CY 2025	2ND FULL FY CY 2026
Administrator (FMC Clinical Manager)	1.00	1.00
(Registered Nurses) RNs	2.00	2.00
Licensed Practical Nurse (LPN)	1.00	1.00
Home Training Nurse	1.00	1.00
Technician (PCT)	6.00	6.00
Dietician	0.50	0.50
Social Worker	0.50	0.50
Maintenance	1.00	1.00
Administrative/Clerical	1.00	1.00
Other (FMC Director of Operations)	0.11	0.11
Other (FMC Chief Technician)	0.11	0.11
Other (FMC In-Service)	0.11	0.11
TOTAL	14.33	14.33

The assumptions and methodology used to project staffing are provided in Section Q, page 104. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.4 in Section Q, page 99. 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:

- FMC Anderson Creek is an existing facility that has demonstrated ability in attracting qualified staff by offering a wide range of personnel benefits and competitive salaries.
- In response to the pandemic’s impact on staffing, Fresenius Medical Care, parent company to BMA, has implemented initiatives such as, sign-on and retention bonuses, increased starting salaries, corporate review of salary scales, intensified recruiting efforts, and comprehensive offerings of Total Rewards to aid in benefiting the employee and their families.
- New employees are required to complete a 10-week training program that includes safety precautions in addition to clinical training.

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 one dialysis station to FMC Anderson Creek pursuant to Condition 2 of the facility need methodology in the 2023 SMFP, for a total of no more than 17 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 54-59, 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.

- (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 in-center, home hemodialysis and peritoneal dialysis patients, as shown in the following table:

FMC Anderson Creek Historical Payor Mix, CY 2022

PAYOR SOURCE	IN-CENTER		HOME HEMODIALYSIS		PERITONEAL DIALYSIS	
	# OF PATIENTS	% OF TOTAL	# OF PATIENTS	% OF TOTAL	# OF PATIENTS	% OF TOTAL
Self-Pay	0.5	0.92%	0.0	0.0%	0.0	0.0%
Insurance*	3.2	5.94%	0.6	19.3%	2.7	30.0%
Medicare*	39.1	72.47%	0.5	17.6%	6.0	66.5%
Medicaid*	0.1	0.14%	0.0	1.0%	0.0	0.0%
Other**	11.1	20.53%	1.9	63.1%	0.3	3.6%
Total	54.0	100.00%	3.0	100.0%	9.0	100.0%

*Including any managed care plans.

**The applicant states on page 66 that "other" includes "Miscellaneous including VA".

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

FMC Anderson Creek	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	46.5%	50.3%
Male	53.5%	49.7%
Unknown	--	--
64 and Younger	64.8%	86.1%
65 and Older	35.2%	13.9%
American Indian	0.0%	1.7%
Asian	4.2%	1.4%
Black or African-American	77.5%	22.2%
Native Hawaiian or Pacific Islander	0.0%	0.2%
White or Caucasian	15.5%	70.7%
Other Race	2.8%	18.2%
Declined / Unavailable	0.0%	0.0%

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 under any obligation to provide services pursuant to any federal regulations.

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 or any similar facilities owned by the applicant or a related entity and located in North Carolina.

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, CY 2026 following project completion, as shown in the following table:

FMC Anderson Creek Projected Payor Mix, CY 2026

PAYOR SOURCE	IN-CENTER		HOME HEMODIALYSIS		PERITONEAL DIALYSIS	
	# OF PATIENTS	% OF TOTAL	# OF PATIENTS	% OF TOTAL	# OF PATIENTS	% OF TOTAL
Self-Pay	0.5	0.92%	0.0	0.0%	0.0	0.0%
Insurance*	3.4	5.94%	0.6	19.3%	2.8	30.0%
Medicare*	41.7	72.47%	0.5	17.6%	6.2	66.5%
Medicaid*	0.1	0.14%	0.0	0.0%	0.0	0.0%
Other**	11.8	20.53%	1.9	63.1%	0.3	3.6%
Total	57.6	100.00%	3.0	100.0%	9.3	100.0%

*Including any managed care plans.

**The applicant states on page 69 that “other” includes “Miscellaneous including VA”.

As shown in the table above, during the second full fiscal year of operation for in-center patients, the applicant projects that 0.92% of total dialysis services will be provided to self-pay patients, 72.47% to Medicare patients and 0.1% to Medicaid patients. The table also illustrates projected payor mix for both home hemodialysis and peritoneal dialysis patients in the second full fiscal year of operation.

On pages 69-70, 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 at FMC Anderson Creek.

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 based on the reasons stated above.

- (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 one dialysis station to FMC Anderson Creek pursuant to Condition 2 of the facility need methodology in the 2023 SMFP, for a total of no more than 17 stations upon project completion.

In Section M, page 73, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-1. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following:

- The facility 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 Central Carolina Technical Community College encouraging the school to include the FMC Anderson Creek 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 one dialysis station to FMC Anderson Creek pursuant to Condition 2 of the facility need methodology in the 2023 SMFP, for a total of no more than 17 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 Harnett County. Facilities may also serve residents of counties not included in their service area.

The table below, taken from Table 9A on page 123 of the 2023 SMFP, lists the existing and approved facilities, certified station, and utilization of dialysis facilities in Harnett County as of December 31, 2021. There are four kidney disease treatment centers providing dialysis services in Harnett County.

HARNETT COUNTY DIALYSIS FACILITIES	PROVIDER	CERTIFIED STATIONS AS OF 12/31/21	# OF IC PATIENTS AS OF 12/31/21	% UTILIZATION AS OF 12/31/21
Dunn Kidney Center	BMA	35	100	71.43%
FMC Anderson Creek	BMA	16	55	85.94%
FMC Angier	BMA	12	24	50.00%
FMC Lillington	BMA	16	55	85.94%

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 Harnett County. The applicant does not project to serve dialysis patients currently being served by another provider.”

The SMFP reports there are currently four operational dialysis facilities with in-center dialysis stations within Harnett County, All of these facilities are 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 FMC Anderson Creek.”

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:

“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, L 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:

- 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.
- Quality care would be provided based on the applicant’s representations about how it will ensure the quality of the proposed services.
- 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 one dialysis station to FMC Anderson Creek pursuant to Condition 2 of the facility need methodology in the 2023 SMFP, for a total of no more than 17 stations upon project completion.

In Section Q, pages 105-109, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 109 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 had not occurred in any of these facilities. After reviewing and considering information provided at all 109 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 dialysis facility for in-center hemodialysis services shall document the need for at least 10 dialysis stations based on utilization of 2.8 in-center patients per station per week as of the end of the first full fiscal year of operation following certification of the facility. An applicant may document the need*

for fewer than 10 stations if the application is submitted in response to an adjusted need determination in the State Medical Facilities Plan for fewer than 10 stations.

-NA- The applicant does not propose to establish a new kidney disease treatment center or dialysis facility.

(b) An applicant proposing to increase the number of in-center 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 full fiscal year of operation following certification of the additional stations.

-C- In Section C, page 27 and on Form C in Section Q, page 83, the applicant projects to serve 56 in-center patients on 17 stations by the end of PY I, which is 3.3 patients per station per week [56 patients / 17 stations = 3.29]. In PY 2, the applicant projects to serve 57 patients on 17 stations, which is 3.4 patients per station per week [57 patients / 17 stations = 3.35). 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.

(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 increase the number of home hemodialysis stations in a dialysis facility dedicated to home hemodialysis or peritoneal dialysis training.

(e) The applicant shall provide the assumptions and methodology used for the projected utilization required by this Rule.

-C- In Section C, pages 26-29, and Section Q, pages 84-89, the applicant provides the assumptions and methodology it uses to project utilization. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.