

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: February 24, 2023

Findings Date: February 24, 2023

Project Analyst: Terris S. Riley

Co-Signer: Gloria C. Hale

Project ID #: E-12300-22

Facility: Fresenius Medical Care of Alexander County

FID #: 090725

County: Alexander

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

Project: Add no more than 5 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 18 dialysis 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. (“BMA” or “the applicant”), proposes to add no more than five in-center (IC) dialysis stations to Fresenius Medical Care of Alexander County (“FMCA”) pursuant to Condition 2 of the facility need methodology for a total of no more than 18 IC dialysis stations upon project completion.

BMA is a wholly owned subsidiary of Fresenius Medical Care Holdings, Inc. (“FMC” or “Fresenius”). FMCA currently provides IC dialysis services and peritoneal dialysis (PD) services.

Need Determination (Condition 2)

Chapter 9 of the 2022 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 135, the county need methodology shows there is not a county need determination for additional dialysis stations in Alexander County.

However, the applicant is eligible to apply for additional dialysis stations in an existing facility pursuant to Condition 2 of the facility need methodology in the 2022 SMFP, if the utilization rate for the dialysis center as reported in the 2022 SMFP is at least 75 percent or 3.0 patients per station per week, as stated in Condition 2.a. Table 9A on page 121 of the 2022 SMFP shows the utilization rate reported for FMCA is 94.23% or 3.76 patients per station per week based on 49 dialysis patients and 13 certified dialysis stations (49 patients / 13 stations = 3.76; $3.76 / 4 = 94.23\%$).

As shown in Table 9D on page 140 of the 2022 SMFP, based on the facility need methodology for dialysis stations, the potential number of stations needed at FMCA is up to five additional stations; thus, the applicant is eligible to apply to add up to five stations during the 2022 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than five new stations to FMCA, which is consistent with the 2022 SMFP calculated facility need determination for up to five dialysis stations; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

Policies

There is one policy in the 2022 SMFP that is applicable to this review. *Policy GEN-3: Basic Principles* on page 30 of the 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

In Section B, pages 21-23, the applicant explains why it believes its application is consistent with Policy GEN-3. On page 23, the applicant states:

“BMA projects utilization will continue to increase while the facility provides dialysis care and treatment in a safe environment, focused on quality patient care, and ensuring

access to care for all patients with proper referral from a nephrology physician (patients cannot self-refer for dialysis treatment). The volume projections for this application are realistic and conservative. BMA consistently provides treatment for the medically underserved and does not discriminate in any manner; all patients are accepted at the facility with proper referral from a physician with admitting privileges. The quality of care provided by the applicant is comparable with or exceeds industry standards for care.”

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 2022 SMFP.
 - The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 based on the following:
 - The applicant adequately documents how the project will promote safety and quality in the delivery of ESRD services in Alexander County.
 - The applicant adequately documents how the project will promote equitable access to ESRD services in Alexander County.
 - The applicant adequately documents how the project will maximize healthcare value for the resources expended.
- (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.

The applicant proposes to add five dialysis stations to FMCA pursuant to Condition 2 of the facility need methodology for a total of 18 stations following project completion.

Patient Origin

On page 115, the 2022 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 Alexander County. Facilities may serve residents of counties not included in their service area.

The following tables illustrate current and projected patient origin for the facility’s IC and PD patients.

FMCA Historical Patient Origin (CY 2021)				
	IC		PD	
	# Patients	% Patients	# Patients	% Patients
Alexander	41.0	91.1%	5.0	83.3%
Iredell	1.0	2.2%	0.0	0.0%
Wilkes	3.0	6.7%	1.0	16.7%
Total	45	100.0%	6.0	100.0%

Sources: Section C, page 25, and ESRD Data Collection Form for 12/31/21
Note: Table may not foot due to rounding.

FMCA Projected Patient Origin FY 2 (CY 2025)				
	IC		PD	
	# Patients	% Patients	# Patients	% Patients
Alexander	62.5	93.6%	7.6	88.4%
Iredell	1.0	3.2%	0.0	0.0%
Wilkes	3.0	1.6%	1.0	11.6%
Total	66.5	100.0%	8.6	100.0%

Source: Section C, pages 25-26
Note: Table may not foot due to rounding.

In Section C, pages 26-29, and immediately following Form C in Section Q, the applicant provides the assumptions and methodology used to project patient origin. The applicant’s assumptions are reasonable and adequately supported based on the following:

- The applicant clearly explains the growth projections for the Alexander County patient population.
- The applicant did not project growth in the patient population dialyzing at FMCA who do not live in Alexander County.

Analysis of Need

In Section C, pages 25-29, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

“Patients with End Stage Renal Disease require dialysis treatment on a regular and consistent basis in order to maintain life. Patients will normally receive three treatments per week. The NC SMFP recognizes that this patient population requires frequent and regular treatment. The need methodology for dialysis stations is focused on four patient shifts per week and recognizes that patients will generally dialyze on a Monday-Wednesday-Friday, morning or afternoon shift schedule, or on a Tuesday-Thursday-Saturday, morning or afternoon shift schedule. Failure to receive dialysis care will ultimately lead to the patient’s demise.

The need that this population has for the proposed services is a function of the individual patient need for dialysis care and treatment.”

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

- According to the 2022 SMFP on page 121, as of December 31, 2020, FMCA was operating at a rate of 3.76 patients per station per week, or 94.23% of capacity.
- Table 9B on page 135 of the 2022 SMFP shows that Alexander County has a deficit of four dialysis stations, which is not enough to trigger a countywide need determination, but which does show there is a need for additional dialysis stations in Alexander County.

Utilization

In Section C, pages 25-26, and on Form C in Section Q, the applicant provides historical and projected utilization, as shown in the table below.

FMCA Current & Projected Utilization								
	Current – CY 2021		FY 2 (CY 2025)		Current – CY 2021		FY 2 (CY 2025)	
	# IC Patients	% IC Patients	# IC Patients	% IC Patients	# PD Patients	% PD Patients	# PD Patients	% PD Patients
Alexander	41.0	91.1%	62.5	93.6%	5.0	83.3%	7.6	88.4%
Iredell	1.0	2.2%	1.0	3.2%	0.0	0.0%	0.0	0.0%
Wilkes	3.0	6.7%	3.0	1.6%	1.0	16.7%	1.0	11.6%
Total	45.0	100.0%	66.5	100.0%	6.0	100.0%	8.6	100.0%

Sources: Section C, pages 25-26, and ESRD Data Collection Form for 12/31/21

Note: Table may not foot due to rounding.

IC Projected Utilization

In Section C, pages 26-29, and in the Form C Utilization subsection of Section Q, the applicant provides the assumptions and methodology used to project patient utilization, which are summarized below.

- The applicant begins its utilization projections with the patient census at FMCA on December 31, 2021. The applicant states that on December 31, 2021, its patient census was comprised of 41 Alexander County patients, 1 Iredell County patient, and 3 Wilkes County patients.
- The applicant projects growth in the Alexander County patient population using the Alexander County 5-year average annual change rate (AACR) of 11.1% as published in the 2022 SMFP on page 135.
- The applicant assumes the patient population from Iredell and Wilkes counties will continue to dialyze at FMCA and adds them to the calculations when appropriate.
- The project is scheduled to begin offering services on January 1, 2023. OY1 is CY 2024 and OY2 is CY 2025.

In Section C, page 27, and immediately following Form C in Section Q, the applicant provides the calculations used to project the patient census for OY1 and OY2, as summarized in the table below.

FMCA IC Projected Utilization	
Starting point of calculations is Alexander County patients dialyzing at FMCA on December 31, 2021.	41
Alexander County patient population is projected forward by one year to December 31, 2022, using the 5-year AACR of 11.1%.	$41 \times 1.111 = 45.6$
Add the four patients from Iredell and Wilkes counties. This is the projected ending census for Interim Year 1.	$45.6 + 4 = 49.6$
Alexander County patient population is projected forward by one year to December 31, 2023, using the 5-year AACR.	$45.6 \times 1.111 = 50.6$
Add the four patients from Iredell and Wilkes counties. This is the projected ending census for Interim Year 2.	$50.6 + 4 = 54.6$
Alexander County patient population is projected forward by one year to December 31, 2024, using the 5-year AACR.	$50.6 \times 1.111 = 56.2$
The four Iredell and Wilkes County patients are added. This is the projected ending patient census for OY1.	$56.2 + 4 = 60.2$
Alexander County patient population is projected forward by one year to December 31, 2025, using the 5-year AACR of 11.1%.	$56.2 \times 1.111 = 62.5$
The patients from the other counties are added. This is the projected census on December 31, 2025 for OY2.	$62.5 + 4 = 66.5$

The applicant projects to serve 60.2 IC patients on 18 stations, which is 3.34 patients per station per week ($60.2 \text{ patients} / 18 \text{ stations} = 3.34$) by the end of OY1 and 66.5 patients on 18 stations, which is 3.69 patients per station per week ($66.5 \text{ patients} / 18 \text{ stations} = 3.69$) by the end of

OY2. This meets the minimum of 2.8 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

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

- FMCA was operating at a rate of 3.76 patients per station per week, or 94.23% of capacity, on December 31, 2020.
- The applicant projects growth in the Alexander County patient population using the Alexander County 5-year AACR as published in the 2022 SMFP.
- The applicant projects no growth for the Iredell or Wilkes County patients.

PD Projected Utilization

The applicant projects to serve 7.9 PD patients by the end of OY1 and 8.6 PD patients by the end of OY2.

- The applicant begins its utilization projections with the Alexander County PD patient census at FMCA on December 31, 2021. According to the ESRD Data Collection Form for December 31, 2021, FMCA was serving 5 PD patients from Alexander County and 1 PD patient from Wilkes County.
- The applicant projects growth in the Alexander County PD patient population using the 5-year AACR for Alexander County of 11.1%, as published in the 2022 SMFP.
- The applicant assumes no growth for the Wilkes County PD patients but adds them to the calculations when appropriate.

In Section C, page 27, and immediately following Form C in Section Q, the applicant provides the calculations used to project the PD patient census for OY1 and OY2, as summarized in the table below.

FMCA PD Projected Utilization	
Begin with the Alexander County patient population as of December 31, 2021.	5
Project the Alexander County patient population forward for one year to December 31, 2022, using the Alexander County Five Year Average Annual Change Rate.	$5 \times 1.111 = 5.6$
Add the one patient from other counties. This is the projected ending census for Interim Year 1.	$5.6 + 1 = 6.6$
Project the Alexander County patient population forward for one year to December 31, 2023, using the Alexander County Five Year Average Annual Change Rate.	$5.6 \times 1.111 = 6.2$
Add the one patient from other counties. This is the projected ending census for Interim Year 2.	$6.2 + 1 = 7.2$
Project the Alexander County patient population forward for one year to December 31, 2024, using the Alexander County Five Year Average Annual Change Rate.	$6.2 \times 1.111 = 6.9$
Add the one patient from other counties. This is the projected ending census for Operating Year 1.	$6.9 + 1 = 7.9$
Project the Alexander County patient population forward for one year to December 31, 2025, using the Alexander County Five Year Average Annual Change Rate.	$6.9 \times 1.111 = 7.6$
Add the one patient from other counties. This is the projected ending census for Operating Year 2.	$7.6 + 1 = 8.6$

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

- The applicant projects growth in the Alexander County patient population using the Alexander County 5-year AACR as published in the 2022 SMFP.
- The applicant projects no growth for the Wilkes County PD patient population.

Access to Medically Underserved Groups

In Section C, page 32, the applicant states:

“... Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, [people with disabilities], [people aged 65 and older], 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, [disability], age or any other grouping/category or basis for being an underserved person.”

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

Medically Underserved Groups	Estimated % of Total Patients in FY 2
Low-income persons	88.4%
Racial and ethnic minorities	32.6%
Women	44.2%
Persons with disabilities	58.1%
Persons 65 and older	27.9%
Medicare beneficiaries	86.0%
Medicaid recipients	88.4%

Source: Section C, page 33

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The applicant provides a statement saying it will provide service to all residents of the service area, including underserved groups, without regard for anything other than the need for dialysis services.
- The applicant states the percentages of patients for each group listed above are based on recent facility experience.

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 five dialysis stations to FMCA pursuant to Condition 2 of the facility need methodology for a total of 18 stations following project completion.

In Section E, page 41, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo: the applicant states maintaining the status quo would result in higher utilization rates and potentially interrupt patient admissions; therefore, this is not an effective alternative.
- Apply for Fewer Than Five Stations: the applicant states that applying for fewer than five stations would result in essentially the same outcome as maintaining the status quo; therefore, this is not an effective alternative.

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 applicant provides reasonable information to explain why it believes the proposed project is the most effective alternative.
- 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
- Information publicly available during the review and used by the Agency

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

- 1. Bio-Medical Applications of North Carolina, Inc. (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 2022 SMFP, the certificate holder shall develop no more than five additional in-center dialysis stations for a total of no more than 18 in-center dialysis stations at Fresenius Medical Care of Alexander County upon project completion.**
 - 3. The certificate holder shall install plumbing and electrical wiring through the walls for no more than 5 additional in-center dialysis stations.**
 - 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 October 1, 2023.**
 - 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 five dialysis stations to FMCA pursuant to Condition 2 of the facility need methodology for a total of 18 stations following project completion.

Capital and Working Capital Costs

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

Construction/Renovation Contracts	\$0
Architect/Engineering Fees	\$0
Non-Medical Equipment/Furniture	\$18,750
Contingency	\$0
Total	\$18,750

Immediately following Form F.1a in Section Q, 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 following:

- The furniture estimate includes all necessary furniture for operation of the facility, to include patient chairs, TVs, computers and office furniture necessary for staff.
- The applicant explains the non-medical equipment is primarily comprised of the water treatment system necessary for dialysis operations. Other items would include signs, project communications and ancillary medical equipment.

In Section F, page 44, the applicant states there are no projected start-up costs or initial operating expenses because FMCA is an existing and operational facility. This information is reasonable and adequately supported because FMCA is an existing facility currently offering ESRD services and will continue to offer ESRD services during and after development of the proposed project.

Availability of Funds

In Section F, pages 42-43, the applicant states the projected capital costs will be funded by accumulated reserves.

Exhibit F.2 contains a letter dated November 15, 2022 from the Senior Vice President & Treasurer of Fresenius Medical Care Holdings, Inc., the parent company of the applicant, authorizing the use of \$18,750 in cash reserves to develop the proposed project. The letter in Exhibit F.2 also states that the 2021 Consolidated Balance Sheet for Fresenius Medical Care Holdings, Inc. shows more than \$301 million in available cash, and total assets of more than \$26.4 billion.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the following:

- The applicant provides a letter from a company executive authorizing the use of funding to develop the proposed project.

- The letter provides information to show that the applicant has adequate cash and assets available to fund the proposed project.

Financial Feasibility

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

Projected Revenues and Operating Expenses		
FMCA	FY 1 – CY 2024	FY 2 – CY 2025
Total Treatments	9,610	10,594
Total Gross Revenues (Charges)	\$60,454,234	\$66,647,911
Total Net Revenue	\$2,988,810	\$3,294,941
Average Net Revenue per Treatment	\$311	\$311
Total Operating Expenses (Costs)	\$2,288,804	\$2,404,629
Average Operating Expense per Treatment	\$238	\$227
Net Revenue/(Loss)	\$700,006	\$890,312

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

- The applicant adequately explains the assumptions used to project revenue, such as projected reimbursement rates, and operating costs, such as salaries.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
 - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
 - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of 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 five dialysis stations to FMCA pursuant to Condition 2 of the facility need methodology for a total of 18 stations following project completion.

On page 115, the 2022 SMFP defines the service area for dialysis stations as “...the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.” Thus, the service area for this facility consists of Alexander County. Facilities may serve residents of counties not included in their service area.

As of December 31, 2020, there was only one facility providing dialysis and/or dialysis home training and support in Alexander County. Information on this facility is provided in the table below.

Alexander County Dialysis Facilities				
Certified Stations and Utilization as of December 31, 2020				
Dialysis Facility	Owner	Location	# of Certified Stations	Utilization
Fresenius Medical Care of Alexander County	BMA	Taylorsville	13	94.23%

Source: Table 9A, Chapter 9, 2022 SMFP (page 121)

In Section G, pages 49-50, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Alexander County. The applicant states:

“FMC Alexander County is the only dialysis facility with in-center stations in Alexander County...

...These stations support the growing patient census at the FMC Alexander County facility.”

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

- The applicant proposes to increase the number of dialysis stations in Alexander County based on Condition 2 of the facility need determination in the 2022 SMFP.
- The applicant adequately demonstrates that the proposed dialysis stations are needed in addition to the existing or approved dialysis stations in Alexander County.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion for 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 five dialysis stations to FMCA pursuant to Condition 2 of the facility need methodology for a total of 18 stations following project completion.

On Form H in Section Q, the applicant provides current and projected staffing for the proposed services, as shown in the table below.

FMCA Current and Projected Staffing		
FTE Position	Current (9/21/2022)	Projected (FYs 1 & 2)
FMC Clinic Manager	1.00	1.00
Registered Nurses	2.00	2.00
Patient Care Technicians	6.00	6.00
Dieticians	1.00	1.00
Social Worker	.50	.50
Maintenance	1.00	1.00
Administration/Business Office	1.00	1.00
FMC Director of Operations	0.25	0.25
FMC Chief Technician	0.25	0.25
FMC In-Service	0.25	0.25
Total	13.25	13.25

The assumptions and methodology used to project staffing are provided immediately 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 51-52, 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 projects sufficient operating expenses for the staff proposed by the applicant.
- The facility is an existing facility, and the applicant bases its staffing on its historical experience.
- 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 five dialysis stations to FMCA pursuant to Condition 2 of the facility need methodology for a total of 18 stations following project completion.

Ancillary and Support Services

In Section I, page 53, the applicant identifies the necessary ancillary and support services for the proposed services. In Section I, pages 53-58, the applicant explains how each ancillary and support service is or will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The facility is an existing facility already providing the necessary ancillary and support services.
- The applicant describes the structure in place at both the corporate level and the facility level for providing the necessary ancillary and support services.

Coordination

In Section I, page 58, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit H-4. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The facility is an existing facility that has existing relationships with local health care and social service providers.
- The applicant provides a letter from the medical director of the facility attesting to the relationship between the medical director's physician practice and the facility.

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 five dialysis stations to FMCA pursuant to Condition 2 of the facility need methodology for a total of 18 stations following project completion.

In Section K, page 61, the applicant states that the project 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 2021 for its existing services, as shown in the table below.

FMCA Historical Payor Mix CY 2021				
Payment Source	# of IC Patients	% of IC Patients	# of PD Patients	% of PD Patients
Self-Pay	2.1	4.63%	0.0	0.0%
Commercial Insurance*	2.6	5.87%	0.8	12.61%
Medicare*	32.4	72.04%	5.1	84.17%
Medicaid*	1.2	2.59%	0.2	3.22%
Misc. (including VA)	6.7	14.88%	0.0	0.0%
Total	45.0	100.00%	6.0	100.00%

*Including any managed care plans

Note: Table may not foot due to rounding.

In Section L, page 66, the applicant provides the following comparison.

	% of Total Patients Served by FMCA during CY 2021	% of the Population of Alexander County
Female	44.2%	48.8%
Male	55.8%	51.2%
Unknown	0.0%	0.0%
64 and Younger	72.1%	79.4%
65 and Older	27.9%	20.6%
American Indian	0.0%	0.6%
Asian	0.0%	1.2%
Black or African-American	18.6%	6.2%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	67.4%	90.2%
Other Race	11.6%	7.0%
Declined / Unavailable	0.0%	0.0%

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 68, the applicant states it has no such obligation.

In Section L, page 68, the applicant states that during the 18 months immediately preceding the application deadline, no civil rights equal access complaints have been filed against FMCA.

Conclusion

The Agency reviewed the:

- Application

- Exhibits to the application

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

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

C

In Section L, page 69, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

FMCA Projected Payor Mix CY 2025				
Payment Source	# IC Patients	% IC Patients	# PD Patients	% PD Patients
Self-Pay	2.8	4.63%	0.0	0.00%
Commercial Insurance*	3.5	5.87%	1.0	12.61%
Medicare*	43.4	72.04%	6.6	84.17%
Medicaid*	1.6	2.59%	0.3	3.22%
Misc. (including VA)	9.0	14.88%	0.0	0.00%
Total	60.2	100.00%	7.9	100.00%

*Including any managed care plans

Note: Table may not foot due to rounding.

On page 69, the applicant provides the assumptions and methodology it uses to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical payor mix at FMCA.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 71, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to add five dialysis stations to FMCA pursuant to Condition 2 of the facility need methodology for a total of 18 stations following project completion.

In Section M, page 72, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-2. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following:

- The applicant states it currently provides access to the facility for health professional training programs and provides a copy of a letter in Exhibit M-2 encouraging the use of the facility by nursing students in their clinical rotations.

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 five dialysis stations to FMCA pursuant to Condition 2 of the facility need methodology for a total of 18 stations following project completion.

On page 115, the 2022 SMFP defines the service area for dialysis stations as “...*the service area is the county in which the dialysis station is located.*” Facilities may serve residents of counties not included in their service area.”

As of December 31, 2020, there was one existing facility providing dialysis and/or dialysis home training and support in Alexander County. Information on this facility is provided in the table below.

Alexander County Dialysis Facilities Certified Stations and Utilization as of December 31, 2020				
Dialysis Facility	Owner	Location	# of Certified Stations	Utilization
Fresenius Medical Care of Alexander County	BMA	Taylorsville	13	94.23%

Source: Table 9A, Chapter 9, 2022 SMFP (page 121)

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 73, the applicant states:

“The applicant does not expect this proposal to have any effect on the competitive climate in Alexander 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 74, the applicant states:

“This is a proposal to add five stations to the FMC Alexander 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 to the patients of the area.”

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

Regarding the impact of the proposal on quality, in Section N, page 74, the applicant states:

“Quality of care is always in the forefront at Fresenius Medical Care related facilities. 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.”

See also Section O of the application as well as any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 74, the applicant states:

“All Fresenius Medical Care related facilities in North Carolina have a history of providing dialysis services to the underserved populations of North Carolina. Each of those facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, [people with disabilities], [people aged 65 and older], 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 any other factor that would classify a patient as underserved.

... Low income and medically underinsured persons will continue to have access to all services provided by Fresenius related facilities.”

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

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

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

- 3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion based on all the reasons described above.

- (19) Repealed effective July 1, 1987.

- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

The applicant proposes to add five dialysis stations to FMCA pursuant to Condition 2 of the facility need methodology for a total of 18 stations following project completion.

On Form O in Section Q, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 125 existing or approved kidney disease treatment facilities located in North Carolina.

In Section O, page 79, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents resulting in an Immediate Jeopardy violation that occurred in any of these facilities. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all 125 facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

G.S. 131E-183 (b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical

center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

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

10 NCAC 14C .2203 PERFORMANCE STANDARDS

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

-NA- FMCA 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, pages 27 and 29, and on Form C in Section Q, the applicant projects that FMCA will serve 60.2 patients on 18 stations, or a rate of 3.34 patients per station per week, as of the end of the first operating year following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

- (c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section C, pages 26-27, and immediately following Form C in Section Q, the applicant provides the assumptions and methodology it used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.