

2REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: September 23, 2022

Findings Date: September 23, 2022

Project Analyst: Ena Lightbourne

Co-Signer: Mike McKillip

Project ID #: E-12238-22

Facility: FMC of Catawba Valley

FID #: 010648

County: Catawba

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

Project: Add no more than 4 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 25 dialysis stations upon completion of this project and Project ID #E-12176-22 (relocate 4)

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 4 in-center (IC) dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 25 IC dialysis stations upon completion of this project and Project ID #E-12176-22 (relocate 4 stations to FKC North Catawba).

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 Catawba 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 facility 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. The utilization rate reported for the facility is 90.00 percent or 3.6 patients per station per week, based on 90 in-center dialysis patients and 25 certified dialysis stations (90 patients / 25 stations = 3.6; 3.6 / 4 = 90.00%).

As shown in Table 9D, based on the facility need methodology for dialysis stations, the potential number of stations needed is up to 5 additional stations; thus, the applicant is eligible to apply to add up to 5 stations during the 2022 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than 4 new stations to the facility, which is less than the 2022 SMFP calculated facility need determination for up to 5 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*.

Policy *GEN-3*, page 30 of the 2022 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, page 22; Section C, page 32; Section L, pages 67-72; Section N, page 75; and

referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant's proposal will promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project will maximize healthcare value in Section B, pages 22-23; Section F, pages 43-48; Section N, page 75; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant's proposal will maximize healthcare value.

The applicant adequately demonstrates how its proposal incorporates the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need as identified by the applicant. Therefore, the application is consistent with policy GEN-3.

Conclusion

The Agency reviewed the:

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

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

- The applicant adequately demonstrates that the application is consistent with the facility need methodology as applied from the 2022 SMFP.
- The applicant adequately demonstrates that the application is consistent with Policy GEN-3 based on:
 - Fresenius Medical Care (parent company) facilities encourage all staff to provide quality care to every patient at every treatment as part of their quality care program.
 - BMA facilities have a history of providing 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 defined as underserved. The majority of the kidney disease treatments are reimbursed by Medicaid and Medicare.
 - The applicant takes on the burden of developing the project by seeking funding from its parent company, Fresenius Medical Care, which ensures dialysis treatment is available at a convenient location.

(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 4 IC dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 25 IC dialysis stations upon completion of this project and Project ID #E-12176-22 (relocate 4 stations).

Patient Origin

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.* Thus, the service area for this facility consists of Catawba County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates historical and projected patient origin.

County	FMC of Catawba Valley Patient Origin			
	Historical Last Full FY CY 2021		Projected 2 nd Full FY CY 2026	
	# of Patients	% of Total	# of Patients	% of Total
Catawba	89.0	100.0%	111.8	100.0%
Total	89.0	100.0%	111.8	100.0%

Source: Section C, pages 25-26

In Section C, pages 26-27, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s patient origin projections are reasonable and adequately supported by the historical (CY2021) patient origin for the facility and projected forward using the Catawba County Five-Year Average Annual Change Rate (AACR) of 5.9%, as published in the 2022 SMFP.

Analysis of Need

In Section C, pages 28-29, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 28, the applicant states:

“BMA operates three dialysis facilities in Catawba County and a CON has been issued to develop a fourth facility, Fresenius Kidney Care North Catawba. The patient population in the BMA facilities of Catawba County continues to increase. The 2022 SMFP reports the Catawba County Five Year Average Annual Change Rate as 5.9%. The Proposed 2023 SMFP reports the Catawba County Five Year Average Annual Change Rate as 7.6%. The increase in the growth rate will result in more dialysis patients residing in Catawba County. More patients mean more stations will be

necessary. BMA proposes to add new dialysis stations to the facility to meet the needs of the patients from the area who choose dialysis at FMC of Catawba Valley.”

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 2022 SMFP. The discussion regarding need methodology found in Criterion (1) is incorporated herein by reference.
- The applicant adequately demonstrates need based on the facility’s projected growth in the patient population.

Projected Utilization

In Section C, page 27, and Section Q, page 85, the applicant provides projected utilization, as illustrated in the following table.

FMC of Catawba County	In-Center patients
Begin with the Catawba County patient population as of December 31, 2021.	89
Project the Catawba County patient population forward for one year to December 31, 2022, using the Catawba County Five-Year AACR. This is the project ending census for Interim Year 1.	$89.0 \times 1.059 = 94.3$
Project the Catawba County patient population forward for one year to December 31, 2023, using the Catawba County Five-Year AACR. This is the project ending census for Interim Year 2.	$94.3 \times 1.059 = 99.8$
Project the Catawba County patient population forward for one year to December 31, 2024, using the Catawba County Five-Year AACR.	$99.8 \times 1.059 = 105.7$
Subtract the 6 patients projected to transfer to the new FKC North Catawba facility upon certification on December 31, 2024. This is the project ending census for Interim Year 3.	$105.7 - 6 = 99.7$
Project the Catawba County patient population forward for one year to December 31, 2025, using the Catawba County Five-Year AACR. This is the projected ending census for Operating Year 1.	$99.7 \times 1.059 = 105.6$
Project the Catawba County patient population forward for one year to December 31, 2026, using the Catawba County Five-Year AACR. This is the projected ending census for Operating Year 2.	$105.6 \times 1.059 = 111.8$

In Section C, pages 26-27 and Section Q, pages 84-86, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The applicant begins its projections with the facility patient census as of December 31, 2021, as reported in the December 2021 ESRD Data Collection Forms submitted to the Agency.
- The applicant projects growth of the Catawba County patient census using the Catawba County Five-Year AACR of 5.9%, as published in the 2022 SMFP.
- The applicant assumes that six patients will transfer their care to the FKC North Catawba upon certification on December 31, 2024 (Project ID# E-12176-22).
- The applicant projects the first operating year of the project will be January 1, 2025–December 31, 2025 and the second operating year will be January 1, 2026–December 31, 2026.

At the end of OY1, FMC of Catawba Valley is projected to serve 105.6 IC patients on 25 stations and at the end of OY2 the facility is projected to serve 111.8 IC patients on 25 stations.

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

- OY1: 4.2 IC patients per station per week or 105.6% ($105.6 \text{ IC patients} / 25 \text{ stations} = 4.224/4 = 1.056$ or 105.6%)
- OY2: 4.4 IC patients per station per week or 111.8% ($111.8 \text{ IC patients} / 25 \text{ stations} = 4.472/4 = 1.118$ or 111.8%)

The projected utilization of 4.2 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).

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

- The applicant’s proposal to add four dialysis stations will meet the need of the projected growth of the facility’s patient population.
- Projected utilization at the end of OY1 exceeds the minimum of 2.8 patients per station per week required by 10A NCAC 14C .2203(b).

Access to Medically Underserved Groups

In Section C, page 32, the applicant states:

“Fresenius Medical Care operates more than 100 dialysis facilities across North Carolina. Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.

...

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.”

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

Medically Underserved Groups	Percentage of Total Patients
Low income persons	28.85%
Racial and ethnic minorities	11.54%
Women	14.42%
Persons with Disabilities	7.69%
Persons 65 and older	31.73%
Medicare beneficiaries	67.31%
Medicaid recipients	28.85%

Source: Section C, page 32

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services. FMC of Catawba Valley is an existing dialysis facility in Catawba County currently providing services to medically underserved groups.

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.

C

The applicant proposes to add no more than 4 IC dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 25 IC dialysis stations upon completion of this project and Project ID #E-12176-22 (relocate 4 stations).

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:

Do Not File for Additional Stations at FMC of Catawba Valley-The applicant states that failure to apply for additional stations would result in a high utilization rate at the facility. The applicant projects a utilization rate of 4.22 by the first operating year without the additional stations, which can potentially interrupt patient admissions.

Apply for Fewer than Four Stations-The applicant states this alternative would result in higher utilization rates as the facility patient census increases.

File for More Than the Five Stations-The applicant states that this alternative is not cost-effective because the facility cannot physically accommodate more than 25 dialysis stations.

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

- Adding the four stations will avoid higher utilization rates that can potentially interrupt patient services.
- 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

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 four additional in-center dialysis stations for a total of no more than 25 in-center stations at FMC of Catawba Valley upon completion of this project and Project ID #E-12176-22 (relocate 4 stations to the FKC North Catawba).**
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 April 3, 2023.**
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 4 IC dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 25 IC dialysis stations upon completion of this project and Project ID #E-12176-22 (relocate 4 stations).

In Section F, page 44, the applicant states that BMA does not project a capital cost for this project because the dialysis machines are leased which will be installed in an existing space previously utilized for dialysis.

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

Financial Feasibility

The applicant provided pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Form F.2, 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.

BMA Lenoir	1st FFY CY 2025	2nd FFY CY 2026
Total Treatments (Form C)	15,635	16,087
Total Gross Revenues (Charges)	\$98,359,771	\$101,204,994
Total Net Revenue	\$4,114,950	\$4,233,982
Average Net Revenue per Treatment	\$263	\$263
Total Operating Expenses (Costs)	\$2,823,065	\$2,827,307
Average Operating Expense per Treatment	\$181	\$176
Net Income	\$1,291,885	\$1,406,675

The assumptions used by the applicant in preparation of the pro forma financial statements are provided 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 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 because the applicant adequately demonstrates 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 4 IC dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 25 IC dialysis stations upon completion of this project and Project ID #E-12176-22 (relocate 4 stations).

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.* Thus, the service area for this facility consists of Catawba County. Facilities may also serve residents of counties not included in their service area.

The table below lists the existing and approved facilities, certified stations, and utilization of dialysis facilities Catawba County as of December 31, 2021.

Facility Name	Certified Stations as of 12/31/2021	# IC Patients as of 12/31/2021	Utilization by Percent as of 12/31/2021	Patients Per Station Per Week
Catawba County Dialysis	21	39	46.42%	1.86
FMC Dialysis Services of Hickory	33	95	71.96%	2.88
FMC of Catawba Valley	25	89	89.00%	3.56
FKC Newton	15	48	80.00%	3.2
Total	94	271		

Source: 2021 ESRD Data Collection Forms

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

“The overall utilization for facilities in Catawba County was 72.07%, or 2.88 patients per station as of December 31, 2021. The overall utilization for the three existing BMA facilities operating in Catawba County was 79.45%, or 3.18 patients per station as of December 31, 2021. All the existing BMA facilities operating in Catawba County were operating above the 70% utilization threshold.

Given the utilization of the BMA facilities, and the growth of the FMC of Catawba Valley facility, BMA does not believe adding four stations at FMC of Catawba Valley will duplicate any services. Rather, the additional stations will ensure continued adequate access to dialysis care for the patient population of the area.”

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 adequately demonstrates that the proposed dialysis stations are needed in addition to the existing or approved dialysis stations.
- There is a facility need determination in the 2022 SMFP for five dialysis stations. The applicant is proposing to add four dialysis stations.

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 4 IC dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 25 IC dialysis stations upon completion of this project and Project ID #E-12176-22 (relocate 4 stations).

In Section H, pages 98-99, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Current FTE Staff	Projected FTE Staff
	As of 5/27/2022	2nd Full Fiscal Year CY 2026
Administrator (FMC Clinic Manager)	1.00	1.00
Registered Nurses (RNs)	2.50	2.50
Technicians (PCT)	4.00	4.00
Dietician	1.00	1.00
Social Worker	1.00	1.00
Maintenance	1.00	1.00
Administration/Business Office	1.00	1.00
Other (FMC Director of Operations)	0.25	0.25
Other (FMC) Chief Technician	0.25	0.25
Other (FMC In-Service)	0.25	0.25
TOTAL	12.25	12.25

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

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

- The applicant has historically maintained adequate staff levels based on their “aggressive” recruiting, advertising efforts, and competitive salaries.
- 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 4 IC dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 25 IC dialysis stations upon completion of this project and Project ID #E-12176-22 (relocate 4 stations).

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. The applicant is not an HMO. Therefore, Criterion (9) is not applicable to this review.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- would be available under a contract of at least 5 years duration;
 - would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - would cost no more than if the services were provided by the HMO; and
 - 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 67, the applicant provides the historical payor mix during CY 2021 for the proposed services, as shown in the table below.

FMC of Catawba Valley Historical Payor Mix 01/01/2021-12/31/2021		
Payor Source	In-Center Dialysis	
	# of Patients	% of Total
Self-Pay	1.2	1.39%
Insurance*	3.3	3.71%
Medicare*	75.1	84.37%
Medicaid*	5.2	5.82%
Other Misc. including VA	4.2	4.71%
Total	89.0	100.00%

*Including any managed care plans.

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

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	14.4%	50.5%
Male	85.6%	49.5%
Unknown	0.0%	0.0%
64 and Younger	68.3%	81.2%
65 and Older	31.7%	18.8%
American Indian	0.0%	1.6%
Asian	0.0%	7.0%
Black or African-American	14.4%	17.0%
Native Hawaiian or Pacific Islander	0.0%	0.0%
White or Caucasian	63.5%	73.8%
Other Race	16.3%	15.2%
Declined / Unavailable	0.0%	0.0%

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

The Agency reviewed the:

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

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

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

C

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

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

In Section L, page 69, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against the facility 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 70, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

FMC of Catawba Valley Projected Payor Mix 01/01/2026-12/31/2026		
Payor Source	In-Center Dialysis	
	# of Patients	% of Total
Self-Pay	1.6	1.39%
Insurance*	4.1	3.71%
Medicare*	94.3	84.37%
Medicaid*	6.5	5.82%
Other Misc. including VA	5.3	4.71%
Total	111.8	100.00%

*Including any managed care plans.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 1.39% of total services will be provided to self-pay patients, 84.37% to Medicare patients and 5.82% to Medicaid patients.

On page 70, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- Payor mix projections are based on recent facility performance.
- The applicant calculates payor mix based upon treatment volumes as opposed to the number of patients and considers the possible change in payor source during the fiscal year.

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

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to add no more than 4 IC dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 25 IC dialysis stations upon completion of this project and Project ID #E-12176-22 (relocate 4 stations).

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:

- FMC of Catawba Valley has a history of allowing health-related education and training programs visit the facility to observe the operation of the unit while patients receive treatment.
- The applicant provides a copy of a letter sent to Catawba Valley Community College encouraging the school to include FMC of Catawba Valley 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 4 IC dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 25 IC dialysis stations upon completion of this project and Project ID #E-12176-22 (relocate 4 stations).

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.*” Thus, the service area for this facility consists of Catawba County. Facilities may also serve residents of counties not included in their service area.

The table below lists the existing and approved facilities, certified stations, and utilization of dialysis facilities Catawba County as of December 31, 2021.

Facility Name	Certified Stations as of 12/31/2021	# IC Patients as of 12/31/2021	Utilization by Percent as of 12/31/2021	Patients Per Station Per Week
Catawba County Dialysis	21	39	46.42%	1.86
FMC Dialysis Services of Hickory	33	95	71.96%	2.88
FMC of Catawba Valley	25	89	89.00%	3.56
FKC Newton	15	48	80.00%	3.2
Total	94	271		

Source: 2021 ESRD Data Collection Forms

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 project to serve dialysis patients currently being served by another provider.

...

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

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

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

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

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

“Quality of care is always in the forefront at Fresenius Medical Care related facilities...Fresenius Medical Care, parent organization for this facility, expects every facility to provide high quality care to every patient at every treatment.”

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

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

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

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

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

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

Conclusion

The Agency reviewed the:

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

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

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

In Section Q, pages 101-105, the applicant identifies the kidney disease treatment facilities located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 132 of this type of facility located in North Carolina.

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

(21) Repealed effective July 1, 1987.

G.S. 131E-183 (b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

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

10A NCAC 14C .2203 PERFORMANCE STANDARDS

(a) *An applicant proposing to establish a new kidney disease treatment center or dialysis facility shall document the need for at least 10 stations based on utilization of 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*

-NA- The applicant does not propose to establish a new kidney disease treatment center or dialysis facility. Therefore, this performance standard is not applicable to this review.

(b) *An applicant proposing to increase the number of dialysis stations in:*
(1) *an existing dialysis facility; or*
(2) *a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need;*

shall document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the additional stations.

- C- In Section C, page 27 and Section Q, page 86, the applicant projects that FMC of Catawba Valley will serve 105.6 in-center patients on 25 stations, or a rate of 4.2 in-center patients per station per week, as of the end of the first operating year following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- (c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section C, pages 26-27, and Section Q, pages 84-86, the applicant provides the assumptions and methodology it uses to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.