

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: October 14, 2022

Findings Date: October 14, 2022

Project Analyst: Donna Donihi

Co-signer: Gloria C. Hale

Project ID #: E-12241-22

Facility: FMC Dialysis Services of Hickory

FID #: 955790

County: Catawba

Applicant: 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 29 stations upon completion of this project and Project ID# E-12176-22 (relocate 8)

REVIEW CRITERIA

G.S. 131E-183(a): The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C

Bio-Medical Applications of North Carolina, Inc. (hereinafter "BMA" or "the applicant") proposes to add no more than 4 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 29 stations at FMC Dialysis Services of Hickory (FMC Hickory) upon completion of this project and Project ID# E-12176-22 (relocate 8).

Need Determination

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 9C, page 141, 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 75.00% or 3.0 patients per station per week, as stated in Condition 2.a. In Table 9A, page 122 of the 2022 SMFP, the utilization rate reported for the facility is 81.06% or 3.24 patients per station per week, based on 107 in-center dialysis patients and 33 certified dialysis stations (107 patients / 33 stations = 3.24; $3.24 / 4 = 0.81$).

As shown in Table 9D, page 140, based on the facility need methodology for dialysis stations, the potential number of stations needed is up to 4 additional stations; thus, the applicant is eligible to apply to add up to four stations during the 2022 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than four new stations to the facility pursuant to Condition 2 in the 2022 SMFP review cycle, which is consistent with the 2022 SMFP calculated facility need determination for up to 4 stations; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

The applicant proposes to add no more than 4 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of more than 29 stations upon completion of this project and Project ID# E-12176-22 (relocate 8).

Policies

There is one policy in the 2022 SMFP which is applicable to this review. *Policy GEN-3: Basic Principles*, on 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 73; Section O, pages 76-78; 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 66-72; Section N, page 74; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant's proposal will promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project will maximize healthcare value in Section B, pages 22-23; Section N, page 73; 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 how the facility's projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need.
- The applicant adequately demonstrates that the application is consistent with Policy GEN-3 based on how it describes the facility's policies and programs,

which promote the concepts of quality, equitable access and maximum healthcare value for 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..

C

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The following table, summarized from data on page 15 of the application, shows the projected number of stations at FMC - Hickory upon project completion.

FMC Hickory		
Stations	Description	Project ID #
33	Total existing certified stations in the SMFP in effect on the day the review will begin	
+4	Stations to be added as part of this project	
-8	Stations to be deleted as part of this project	E-12176-22
29	Total stations upon completion of proposed project and previously approved projects	

In Section C, page 25, the applicant documents that FMC-Hickory did not provide home hemodialysis (HH) or peritoneal dialysis (PD) modalities during its last full fiscal year (CY 2021). On page 26, the applicant projects that FMC-Hickory will not provide HH or PD modalities during the second full fiscal year following project completion.

Patient Origin

On page 115, the 2022 SMFP defines the service area for the county need methodology 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 application is Catawba County. Facilities may serve residents of counties not included in their service area.

The following table illustrates current and projected patient origin.

FMC-Hickory Current & Projected Patient Origin				
	Current (CY 2021)		Projected FY 2 (2026)	
	In-center		In-center	
	# Patients	% Patients	# Patients	% Patients
Catawba	82.0	86.3%	84.5	86.7%
Alexander	3.0	3.2%	3.0	3.1%
Burke	6.0	6.3%	6.0	6.2%
Caldwell	4.0	4.2%	4.0	4.1%
Total	95.0	100.0%	97.5	100.0%

Source: Section C, pages 25-26 of the application

In Section C, pages 25-28, 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 begins with the historical December 31, 2021 patient census.
- The applicant applies the Average Annual Change Rate (AACR) published in the 2022 SMFP, 5.9%, for predicting growth of the Catawba County patients.
- The applicant assumes the 13 in-center patients residing in Alexander, Burke, and Caldwell Counties will continue to dialyze at FMC-Hickory and does not project any growth.
- The proposed new stations are projected to be certified as of December 31, 2024.
- Operating Year (OY) 1, the first full FY is CY2025. OY2 is CY2026.

The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, page 30, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 29, 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 Rate Change will increase to 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 propose to add new dialysis stations to the facility to meet the needs of the patients from the area who choose dialysis at FMC Dialysis Services of Hickory.

Patients with End Stage Renal Disease require dialysis treatment on a regular and consistent basis in order to maintain life. Patients will normally receive treatments three times per week.

The applicant has identified the population to be served as 92.8 in-center dialysis patients dialyzing with the facility as of the end of the first Operating Year of the project. This equates to a utilization rate of 80%, or 3.2 patients per station and exceeds the minimum required by the performance standard.”

The information is reasonable and adequately supported based on the following:

- According to the 2022 SMFP, as of December 31, 2020, FMC Hickory was operating at a rate of 3.24 patients per station per week, or 81.06% of capacity. The applicant begins its utilization projections with the IC patient census at FMC- Hickory on December 31, 2021. The applicant states that on December 31, 2021, its IC patient census was comprised of 82 Catawba County patients.
- The applicant applies the County AACR as provided in the 2022 SMFP to project growth in Catawba County patient utilization and projects no growth for the patients from other counties being served at FMC-Hickory.
- The applicant subtracts the 22 patients projected to transfer to new FKC North Catawba facility upon certification on December 31,2024.
- The applicant adds the 13 patients from other counties each year, with no future growth.
- The applicant assumes the out-of-state patients will continue to dialyze at the facility.
- The applicant’s need analysis results in utilization which exceeds the minimum required by the performance standard.

Form C Utilization as Provided by Applicant in Section Q

Form C Utilization	Last Full FY CY2021	1st Full FY CY2025	2nd Full FY CY2026
<i>In-Center Patients</i>			
# of Patients at the Beginning of the Year	107	110	93
# of Patients at the End of the Year	95	93	98
Average # of IC Patients during the Year	101	102	95
# of Treatments / Patient / Year	148	148	148
<i>Total # of Treatments</i>	15,184	15,038	14,088

In Section C, pages 25-27 and Section Q, pages 84-86, the applicant provides the assumptions and methodology used to project in-center utilization, which are summarized below.

- The first full FY is CY2025, the period from January 1, thru December 31, 2025.
- The second full FY is CY2026,
- Projections begin with the facility census as of December 31, 2021.
- The applicant grows the Catawba County patient census by 5.9%, the 5-year AACR, as found in the 2022 SMFP, page 135.
- The out-of-state patients are assumed to continue to dialyze at the facility.
- The proposed new stations will be installed and certified as of December 31, 2023.

Projected In-Center Utilization

In Section C, page 27, and immediately following Form C in Section Q, the applicant provides the projected utilization, as summarized in the following table.

In – Center Methodology	
Begin with the Catawba County Patient population as of December 31, 2021	82
Project the Catawba County patient population forward one year to December 31,2022, using the Catawba County Five Year Average Annual Change Rate.	$82.0 \times 1.059 = 86.8$
Add 13 patients from other counties. This is the projected ending census for Interim Year 1.	$86.8 + 13 = 99.8$
Project the Catawba County patient population forward one year to December 31,2023, using the Catawba County Five Year Average Annual Change Rate of 5.9%	$86.8 \times 1.059 = 92.0$
Add 13 patients from other counties. This is the projected ending census for Interim Year 2.	$92.0 + 13 = 105.0$

Project the Catawba County patient population forward one year to December 31,2024, using the Catawba County Five Year Average Annual Change Rate.	$92.0 \times 1.059 = 97.4$
Add 13 patients from other counties. This is the projected ending census for Interim Year 3.	$97.4 + 13 = 110.4$
Subtract the 22 patients projected to transfer to the new FKC North Catawba facility upon certification on December 31,2024	$97.4 - 22 = 75.4$
Project the Catawba County patient population forward one year to December 31,2025, using the Catawba County Five Year Average Annual Change Rate.	$75.4 \times 1.059 = 79.8$
Add 13 patients from other counties. This is the projected ending census for <i>Operating Year 1</i> .	$79.8 + 13 = 92.8$
Project the Catawba County patient population forward one year to December 31,2026, using the Catawba County Five Year Average Annual Change Rate.	$79.8 \times 1.059 = 84.5$
Add 13 patients from other counties. This is the projected ending census for <i>Operating Year 2</i> .	$84.5 + 13 = 97.5$

As shown in the table above, the applicant projects to serve 92.8 patients on 29 stations, which is 3.2 patients per station per week ($92.8 \text{ patients} / 29 \text{ stations} = 3.2$), by the end of OY1 and 97.5 patients on 29 stations, which is 3.36 patients per station per week ($97.5 \text{ patients} / 29 \text{ stations} = 3.36$), by the end of OY2. This meets the minimum of 2.8 patients per station as required by 10A NCAC 14C .2203(b).

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

- According to the 2022 SMFP, FMC-Hickory was operating at a rate of 3.24 patients per station per week, or 81.06% of capacity, on December 31, 2020.
- The applicant projects future utilization based on historical utilization.
- The applicant projects the growth of the Catawba County patient census using the Five-Year AACR of 5.9% as reported in the 2022 SMFP.
- The projected utilization rate by the end of OY1 exceeds the minimum standard of 2.8 patients per station per week.
- The applicant subtracts the number of patients who will transfer to FKC North Catawba.

Access to Medically Underserved Groups

In Section C.6, page 32, the applicant discusses access to the facility’s services, stating:

“.... Fresenius Medical Care has a long history of providing dialysis services to the underserved populations of North Carolina...Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, [people with disabilities], [persons 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 for each medically underserved group to be served in the second year of operation on page 32, as summarized in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low income persons	33.98%
Racial and ethnic minorities	14.56%
Women	19.42%
Persons with Disabilities	8.74%
Persons 65 and older	26.21%
Medicare beneficiaries	80.58%
Medicaid recipients	33.98%

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 Fresenius corporate policy commits to provide services to all patients referred for ESRD 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 the following reasons:

- The applicant adequately identifies the population to be served
- The applicant adequately explains why the population to be served needs the services proposed in this application
- Projected utilization is reasonable and adequately supported
- The applicant describes the extent to which all residents, including underserved groups, are likely to have access to the proposed services and adequately supports its assumptions

- (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

Bio-Medical Applications of North Carolina, Inc. (hereinafter “BMA” or “the applicant”) proposes to add no more than 4 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 29 stations at FMC Dialysis Services of Hickory (FMC Hickory) upon completion of this project and Project ID# E-12176-22 (relocate 8).

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 that the failure to apply for additional stations leads to higher utilization rates and can lead to interruption of patient admission; thus, this alternative is not the most effective.

- ***Apply for Fewer Stations:*** the applicant states that applying for fewer stations would result in essentially the same outcome as maintaining the status quo and that patients may be turned away due to lack of capacity; therefore, this is not an effective alternative.

Based on the explanations above, the applicant determined that its project as proposed is the most effective alternative.

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 1. Bio-Medical Applications of North Carolina, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. Pursuant to Condition 2 of the facility need determination in the 2022 SMFP, the certificate holder shall develop no more than four additional in-center dialysis stations for a total of no more 29 stations at FMC Dialysis Services of Hickory upon completion of this project and Project ID# E-12176-22 (relocate 8).**
- 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 1, 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

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Capital and Working Capital Costs

In Section F, pages 42 and 44, respectively, the applicant states there will be no capital and no start-up or initial operating expenses associated with the proposed project since this is an existing facility that is already operational.

Financial Feasibility

The applicant provides pro forma financial statements for the first two full operating years following completion of the project. In Form F.2, page 91, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as summarized in the table below.

FMC Hickory Projected Revenue and Operating Expenses

	1 st Full FY	2 nd Full FY
	CY2025	CY2026
Total In-Center Treatments	15,038	14,088
Total Gross Revenues (Charges)	\$94,606,833	\$88,628,496
Total Net Revenue	\$4,021,165	\$3,767,062
Avg Net Revenue per Treatment	\$267	\$267
Total Operating Expenses (Costs)	\$3,812,742	\$3,755,744
Avg Op. Expense per Treatment	\$254	\$267
Net Income	\$208,423	\$11,318

Source: Form F.2

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

- Contractual adjustments are calculated by payor class for each year.
- Salaries are projected to increase at 2% annually.
- 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, and
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion because 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 costs and revenues 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

Bio-Medical Applications of North Carolina, Inc. (hereinafter “BMA” or “the applicant”) proposes to add no more than 4 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 29 stations at FMC Dialysis Services of Hickory (FMC Hickory) upon completion of this project and Project ID# E-12176-22 (relocate 8).

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.” FMC Dialysis Services of Hickory located in Catawba County. Thus, the service area for this application is Catawba County. Facilities may serve residents of counties not included in their service area.

According to Table 9A on page 126 of the 2022 SMFP and the information provided by the applicant in Section G, page, 49, there are 4 existing dialysis facilities in Catawba County. Information on these dialysis facilities, from Table 9A of the 2022 SMFP is summarized below.

Catawba County Dialysis Facilities Certified Stations and Utilization as of December 31, 2020					
Dialysis Facility	# Certified Stations	#IC Patients	Utilization by Percent	Patients Per Station per week	Facility Need Determination
Catawba County Dialysis	16	41	64.06%	2.56	0
FMC Dialysis Services of Hickory	33	107	81.06%	3.24	4
FMC Catawba Valley	25	90	90.00%	3.60	5
FKC Newton	15	28	46.67%	1.86	0
Total	89	266	70.44%		

Source Table 9A, 2022 SMFP.

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 Catawba County. The applicant states:

“This is an application based upon the facility performance and demonstrated need at FMC Dialysis Services of Hickory facility. The need addressed by this application is not specific to Catawba County as a whole.”

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 FMC Dialysis Services of Hickory needs additional stations to serve its existing and projected patient population, based on Condition 2 of the facility need determination in the 2022 SMFP
- The applicant adequately demonstrates that the proposed additional stations are needed in addition to the existing and approved stations in Catawba 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 based on the reasons stated 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

Bio-Medical Applications of North Carolina, Inc. (hereinafter “BMA” or “the applicant”) proposes to add no more than 4 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 29 stations at FMC Dialysis Services of Hickory (FMC Hickory) upon completion of this project and Project ID# E-12176-22 (relocate 8).

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

POSITION	Current FTE Positions	FTE Positions 1ST FY 2025	FTE Positions 2nd FY 2026
Administrator	1.00	1.00	1.00
RN	7.00	7.00	7.00
Patient Care Technician (PCT)	7.00	7.00	7.00
Dietician	1.00	1.00	1.00
Social Worker	1.00	1.00	1.00
Maintenance	1.00	1.00	1.00
Administration/Business Office	1.00	1.00	1.00
FMC Director Operations	0.25	0.25	0.25
FMC Chief Technician	0.25	0.25	0.25
FMC In-Service	0.25	0.25	0.25
Total	19.75	19.75	19.75

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 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 facility is an existing facility and the applicant bases its staffing on its historical experience providing dialysis services at the facility
- The applicant has existing policies in regard to recruitment, training and continuing education

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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Ancillary and Support Services

In the table in Section I, page 53, the applicant identifies each ancillary and support service listed in the application as necessary for the proposed services. On pages 53-58, the applicant explains how each ancillary and support service is made available.

- 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 59, the applicant describes its existing relationships with other local health care and social service providers.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant discusses its existing relationships with local health care and social service providers
- The applicant has agreements in place coordinating lab services, hospital services, and transplant 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.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

- (i) would be available under a contract of at least 5 years duration;
- (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
- (iii) would cost no more than if the services were provided by the HMO; and
- (iv) would be available in a manner which is administratively feasible to the HMO.

NA

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

In Section K, page 61, the applicant states that “*the project does not involve construction nor renovation of 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

Bio-Medical Applications of North Carolina, Inc. (hereinafter “BMA” or “the applicant”) proposes to add no more than 4 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 29 stations at FMC Dialysis Services of Hickory (FMC Hickory) upon completion of this project and Project ID# E-12176-22 (relocate 8).

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.

FMC-Hickory Historical Payor Mix CY 2021		
Payment Source	# of Patients	% of Patients
Self-Pay	2.2	2.34%
Commercial Insurance	4.5	4.74%
Medicare	79.7	83.88%
Medicaid	5.1	5.39%
Misc. (including VA)	3.5	3.65%
Total	95	100.0%

In Section L, page 67, the applicant provides the following comparison.

	Percentage of Total Patients Served by FMC Hickory during CY 2020	Percentage of the Population of Catawba County
Female	19.4%	50.5%
Male	80.6%	49.5%
64 and Younger	73.8%	81.2%
65 and Older	26.2%	18.8%
American Indian	0.0%	1.6%
Asian	0.0%	7.0%
Black or African American	27.2%	17.0%
White or Caucasian	67.0%	73.8%
Other Race	0.0%	15.2%

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 68 the applicant states that it 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 68, 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 identified in Section A, Question 4.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

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

**Second Full FY of Operation following
Project Completion
CY2026**

Payor Category	IC Patients	
	Number	% of Total
Self-Pay	2.3	2.34%
Insurance *	4.6	4.74%
Medicare *	81.8	83.88%
Medicaid *	5.3	5.39%
Misc. (including VA)	3.6	3.65%
Total	97.5	100.00%

*Including any managed care plans
Totals may not sum due to rounding

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 2.34% of IC services will be provided to self-pay patients;

83.88% of IC services, will be provided to Medicare patients; and 5.39% of IC services, will be provided to Medicaid patients.

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 based on the following:

- The applicant bases payor mix upon treatment volumes rather than patients.
- The applicant bases future payor mix percentages on recent facility performance.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

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

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

Bio-Medical Applications of North Carolina, Inc. (hereinafter "BMA" or "the applicant") proposes to add no more than 4 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 29 stations at FMC Dialysis

Services of Hickory (FMC Hickory) upon completion of this project and Project ID# E-12176-22 (relocate 8).

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-1. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- The applicant currently provides applicable health professional training programs in the area with access to the facility.
- The applicant provides a copy of the letter sent to Catawba Valley Community College offering training opportunities.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

- (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

Bio-Medical Applications of North Carolina, Inc. (hereinafter “BMA” or “the applicant”) proposes to add no more than 4 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 29 stations at FMC Dialysis

Services of Hickory (FMC Hickory) upon completion of this project and Project ID# E-12176-22 (relocate 8).

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.*” FMC Hickory is located in Catawba County. Thus, the service area for this application is Catawba County. Facilities may serve residents of counties not included in their service area.

Information on the Catawba County dialysis facilities, from Table 9A of the 2022 SMFP, is summarized below:

Catawba County Dialysis Facilities Certified Stations and Utilization as of December 31, 2020					
Dialysis Facility	# Certified Stations	#IC Patients	Utilization by Percent	Patients Per Station per Week	Facility Need Determination
Catawba County Dialysis	16	41	64.06%	2.56	0
FMC Dialysis Services of Hickory	33	107	81.06%	3.24	4
FMC Catawba Valley	25	90	90.00%	3.60	5
F KC Newton	15	28	46.67%	1.86	0
Total	89	266	70.44%		

Source Table 9A, 2022 SMFP.

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 Catawba County. The applicant does not project to serve dialysis patients currently being served by another provider. The projected patient population for the facility begins with the current patient population, projected patient transfers, and growth of that population consistent with the Catawba County Five Year Average Annual Change Rate published in the 2022 SMFP.”

Regarding the impact of the proposal on cost effectiveness, in Section N pages 73-74, the applicant states:

“Fresenius Medical Care related facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid.

...

Fresenius Medical Care related facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients.

...

Approval of this application will allow the facility to continue serving patients residing in the area of the facility. 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, 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. Our organizational mission statement captures this sentiment very well:

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

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

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

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

Fresenius related facilities in North Carolina have historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for being an underserved person. Low income and medically underinsured persons will continue to have access to all services provided by Fresenius related facilities.”

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

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a

positive impact on cost-effectiveness, quality, and access because the applicant 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 the reasons stated 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

Bio-Medical Applications of North Carolina, Inc. (hereinafter "BMA" or "the applicant") proposes to add no more than 4 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 29 stations at FMC Dialysis Services of Hickory (FMC Hickory) upon completion of this project and Project ID# E-12176-22 (relocate 8).

In Section Q Form O, 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 over 120 dialysis facilities owned, operated, or managed by a Fresenius Medical Care related entity and located in North Carolina.

In Section O, page 79 , the applicant states that, during the 18 months immediately preceding the submittal of the application, no Fresenius related facility has been found

to have had an incident related to quality of care that resulted in a finding of “*Immediate Jeopardy*”. After reviewing and considering information provided by the applicant and considering the quality of care provided at all Fresenius 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 application is conforming with all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. The specific criteria are 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- FMC Hickory is an existing facility. Therefore, this Rule is not applicable to this review.

(b) *An applicant proposing to increase the number of dialysis stations in:*

(1) *an existing dialysis facility; or*

(2) *a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need;*

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

- C- In Section C, page 27, and on Form C in Section Q, the applicant projects that FMC-Hickory will serve 92.8 patients on 29 stations or a rate of 3.2 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.