

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: February 20, 2026

Findings Date: February 20, 2026

Project Analyst: Gregory F. Yakaboski

Co-Signer: Mike McKillip

Project ID #: L-12723-25

Facility: FMC Tarboro

FID #: 150155

County: Edgecombe

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

Project: Add no more than 1 in-center dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 16 stations upon completion of this project and Project ID# L-12696-25 (relocate 1 station)

### REVIEW CRITERIA

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

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

**C**

Bio-Medical Applications of North Carolina, Inc. (hereinafter referred to as “BMA” or the “applicant”) proposes to add no more than one in-center dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 16 stations upon completion of this project and Project ID# L-12696-25 (relocate 1 station from FMC Tarboro to Edgecombe Home Dialysis).

The application for Project ID# L-12696-25 (relocate 1 station from FMC Tarboro to Edgecombe Home Dialysis) was filed on September 15, 2025, the review was an October 2025 review. The project was conditionally approved on December 19, 2025, and a Certificate was issued effective January 23, 2026. The application for this review was filed on November 13, 2025, and the review was a December 2025 review. Therefore, at the time this application was

filed FMC Tarboro was certified for 16 in-center stations. Upon completion of the conditionally approved Project ID# L-12696-25 (relocate 1 station from FMC Tarboro to Edgecombe Home Dialysis) FMC Tarboro will be certified for 15 in-center stations. This project, if approved, will bring FMC Tarboro back to 16 in-center stations.

### **Need Determination (Condition 2)**

Chapter 9 of the 2025 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table 9C on page 136 of the 2025 SMFP, the county need methodology shows there is not a county need determination for additional dialysis stations anywhere in the state.

However, the applicant is eligible to apply for additional dialysis stations in an existing facility pursuant to Condition 2 of the facility need methodology in the 2025 SMFP, if the utilization rate for the facility as reported in the 2025 SMFP is at least 75 percent or 3.0 patients per station per week or greater, as stated in Condition 2.a. The utilization rate reported for the facility is 100.0% or 4.0 patients per station per week, based on 60 in-center dialysis patients and 15 certified dialysis stations (60 patients / 15 stations =4.0, 4.0/ 4= 1.0 or 100.0%).

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

The applicant proposes to add no more than one new station to the facility, which is consistent with the 2025 SMFP calculated facility need determination for up to six stations; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

### **Policies**

There is one policy in the 2025 SMFP that is applicable to this review, *Policy GEN-5: Access to Culturally Competent Healthcare*.

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

*“A certificate of need (CON) applicant applying to offer or develop a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will provide culturally competent healthcare that integrates principles to increase health equity and reduce health disparities in underserved communities. The delivery of culturally competent healthcare requires the implementation of systems and training to provide responsive, personalized care to individuals with diverse backgrounds, values, beliefs, customs, and languages. A certificate of need applicant shall identify the underserved populations and communities it will serve, including any disparities or unmet needs of either, document its strategies to provide culturally competent programs and services,*

*and articulate how these strategies will reduce existing disparities as well as increase health equity.*

*CON applications will include the following:*

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

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

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

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

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

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

In Section B, pages 20-24, the applicant explains why it believes its application is consistent with Policy GEN-5. The applicant states that FMC Tarboro is located in Edgecombe County, North Carolina, thus the relevant service area for the proposed project is Edgecombe County. The applicant states that according to the 2024 ESRD Data Collection Form for FMC Tarboro, as of December 31, 2024, the facility serviced a total of 63 in-center dialysis patients of which 59, or 93.7% were residents of Edgecombe County. The applicant states that the facility demographics below, which include members of medically underserved communities, are reflective of the relevant service area, the majority of the patients dialyzing at the facility residing in Edgecombe County.

- The applicant states that Fresenius Kidney Care (FKC) has developed a Health Equity Strategic Plan that outlines organizational goals, objectives, actions, and resources to ensure that as an organization, providing culturally competent services to all members of the medically underserved community who are choosing to receive dialysis treatment within a FKC or FKC affiliated facility.

- The strategic plan was developed with an understanding that healthcare organizations such as ours have a central role in achieving health equity and should understand, identify, and reduce health disparities by identifying and addressing health related social needs (HRSN).
- The applicant states that part of the FKC Health Equity Strategic Plan for 2024-2026, a 4-part training program was developed, Journey to Cultural Competency, for all direct patient care clinical staff to ensure that culturally competent services are provided to members of medically underserved communities.
- The applicant states that development of this program along with our overall Health Equity Strategic Plan reinforces our mission to deliver superior care that improves the quality of life of every patient, every day, setting the standard by which others in the healthcare industry are judged.
- The applicant states that the commitment is reflected in the mission to deliver superior care that improves the quality of life of every patient, every day, setting the standard by which others in the healthcare industry are judged.
- The applicant states that the 4-part training starts the employee on a journey of providing culturally competent care through understanding
  - Social determinants of health
  - Identifying unconscious biases
  - Building trust
  - fostering an inclusive environment for all
- The applicant states that the commitment is also reflected in the mission to deliver superior care that improves the quality of life of every patient, every day, setting the standard by which others in the healthcare industry are judged.
- The applicant states that recognizing and addressing the unique culture, language, health literacy, social and economic needs of our diverse patient population is a fundamental step towards the goal.
- The applicant states that the strategies are reflective of cultural competency in that they have been designed to provide our staff with knowledge, skills, and resources necessary to provide care to patients with diverse values, beliefs, and behaviors, including the tailoring of health care delivery to meet patient's social, cultural, and linguistic needs with a better understanding of social determinants of health, moving from unconscious bias to intentional inclusion, and building trust and fostering an inclusion.
- The applicant states that all dialysis facilities in the United States are expected to demonstrate a commitment to health equity and implement a strategic plan for health equity as part of the End-Stage Renal Disease Quality Improvement Program.
- The applicant states that measures and periodically assess increased equitable access to healthcare services and reductions in health disparities in underserved communities.

The applicant provides data below that reflects patient demographics at the facility.

Facility Demographics	# of Patients	% of Patients
Low-income persons	55	91.7%
Racial and ethnic minorities	49	81.7%
Women	28	46.7%
Handicapped persons	30	50.0%
The Elderly	10	16.7%
Medicare beneficiaries	48	80.0%
Medicaid beneficiaries	55	91.7%
American Indian	-	-
Asian	-	-
Black or African American	47	78.3%
Native Hawaiian or Pacific Islander	-	-
White or Caucasian	13	21.7%
Other Race	-	-
Declined/Unavailable	-	-

Source: Section B, page 21 of the application

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the application is consistent with the facility need methodology as applied from the 2025 SMFP.
- The applicant adequately demonstrates that the application is consistent with Policy: GEN -5 based on the following:
  - The applicant adequately demonstrates how the project will provide culturally competent healthcare.
  - The applicant adequately describes the demographics of Wake County with a focus on the medically underserved communities in Wake County.
  - The applicant documents its strategies to provide culturally competent programs and services and the applicant demonstrates how these strategies will reduce existing disparities and increase health equity.
  - The applicant adequately describes how it will measure and periodically assess increased equitable access to healthcare services and reduction in health disparities in underserved communities.

(2) Repealed effective July 1, 1987.

(3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which

all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

**C**

The applicant proposes to add no more than one in-center dialysis station to FMC Tarboro pursuant to Condition 2 of the facility need methodology for a total of no more than 16 stations upon completion of this project and Project ID# L-12696-25 (relocate 1 station from FMC Tarboro).

On page 113, the 2025 SMFP defines the service area for dialysis stations as “the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.” FMC Tarboro is in Edgecombe County. Thus, the service area for this facility consists of Edgecombe County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates historical and projected patient origin at FMC Tarboro.

County	Historical (CY2024)		Third Full FY of Operation following Project Completion (CY2028)	
	Patients	% of Total	Patients	% of Total
Edgecombe	59.0	93.7%	59.0	93.7%
Halifax	2.0	3.2%	2.0	3.2%
Nash	1.0	1.6%	1.0	1.6%
Pitt	1.0	1.6%	1.0	1.6%
<b>Total</b>	<b>63.0</b>	<b>100.0%</b>	<b>63.0</b>	<b>100.0%</b>

Source: Tables on pages 25-26 of the application.

In Section C.3, pages 25-27, and the Form C Utilization subsection of Section Q, pages 77-79, the applicant provides the assumptions and methodology used to project patient origin. The applicant’s assumptions are reasonable and adequately supported based on the following:

- The applicant clearly explains how it projected growth in Edgecombe’s County patient population. Projected patients and patient origin are based on the last full year of historical data (CY2024). The applicant does not project any growth in the Edgecombe County population because the building housing the facility has a physical capacity of just 16 in-center stations. The facility is currently operating at 98.4% of capacity. Additional patients would require additional stations beyond 16 in-center stations, which is not physically possible at the current location.
- The applicant did not project growth in the number of patients at FMC Tarboro who do not live in Edgecombe County.

**Analysis of Need**

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

*“The need that this population has for the proposed services is a function of the individual patient’s need for dialysis care and treatment. This question specifically addresses the need that the population to be served for the proposed project. The applicant has identified the population to be served as 63 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 98.4%, or 3.94 patients per station and exceeds the minimum required by the performance standard, thus justifying the need for the total number of existing, approved, and proposed in-center dialysis stations at the FMC Tarboro facility.”*

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

- The applicant demonstrates eligibility to add dialysis stations to its facility under Condition 2 of the facility need methodology, as stated in the 2025 SMFP, Table 9D, page 137. The discussion regarding the need methodology found in Criterion (1) is incorporated herein by reference.
- The applicant adequately demonstrates need based on the facility’s existing patient census and inability to add additional in-center stations at the facility due to building constraints.
- Per Table 9A, page 122, of the 2025 SMFP, as of December 31, 2023, the utilization rate reported for the FMC Tarboro facility is 100.0% or 4.0 patients per station per week, based on 60 in-center dialysis patients and 15 certified dialysis stations (60 patients / 15 stations = 4.0: 4.0/ 4= 1.0 or 100.0%).

Projected Utilization

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

The applicant begins with the Edgecombe County IC patients as of December 31, 2024.	59.0
The applicant projects Edgecombe County IC patients forward one year to December 31, 2025, at no patient population growth.	59.0
The applicant projects Edgecombe County IC patients forward one year to December 31, 2026, at no patient population growth.	59.0
The applicant projects Edgecombe County IC patients forward one year to December 31, 2027, at no patient population growth.	59.0
The applicant adds the 4 non-Edgecombe County IC patients. This is the projected ending census for <b>Operating Year 1 (CY2027)</b> .	59 + 4 = <b>63</b>
The applicant projects Edgecombe County IC patients forward one year to December 31, 2028, at no patient population growth.	59
The applicant adds the 4 non-Edgecombe County IC patients. This is the projected ending census for <b>Operating Year 2 (CY2028)</b> .	59 + 4 = <b>63</b>

Therefore, at the end of OY1 (CY2027) the facility is projected to serve 63 in-center patients and at the end of OY2 (CY2028) the facility is projected to serve 63 in-center patients.

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

- OY1: 3.94 patients per station per week or 98.5% utilization (63 patients / 16 stations = 3.9375,  $3.94 / 4 = 0.985$  or 98.5%).
- OY2: 3.94 patients per station per week or 98.5% utilization (63 patients / 16 stations = 3.9375,  $3.94 / 4 = 0.985$  or 98.5%).

The projected utilization of 3.94 patients per station per week at the end of OY1 meets the minimum standard of 2.8 in-center patients per station per week required by 10A NCAC 14C .2203(b).

In Section C.3, pages 25-27, and the Form C Utilization subsection of Section Q, pages 77-79, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The applicant projects the first two full operating years of the project will be January 1, 2027–December 31, 2027 (CY2027) and January 1, 2028–December 31, 2028 (CY2028).
- The applicant begins its projections with the facility census as of December 31, 2024. This information is reported in the 2024 ESRD Data Collection forms submitted to the Agency. The facility reported 63 in-center patients receiving dialysis services at FMC Tarboro. Of the 63 patients, 59 reside in Edgecombe County and 4 are non-Edgecombe County residents.
- The Edgecombe County Five-Year Average Annual Change Rate of 6.7%, as published in the 2025 SMFP, Table 9B, page 133.
- However, the applicant does not project any growth for the 59 patients from Edgecombe County dialyzing at the FMC Tarboro facility. The reason the number of patients from Edgecombe County is held constant is because the facility is currently certified for 16 in-center stations and is operating at 98.4% of its station capacity. Due to physical constraints in the building housing the facility the building cannot accommodate any additional in-center stations. The applicant states that *“more patients would require more stations that the facility does not have the capacity to add.”*
- The applicant projects that the four in-center patients residing in counties contiguous to Edgecombe (Halifax, Nash and Pitt) would *“continue dialysis at FMC Tarboro as a function of patient choice. These patients are assumed to continue dialysis with at facility”*. However, the applicant does not project growth for the 4 patients residing outside of the Edgecombe County service area.

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

- The applicant projects future utilization based on the most recent historical patient

census.

- The applicant does not project any growth for the 59 patients from Edgecombe County dialyzing at the FMC Tarboro facility. The reason the number of patients from Edgecombe County is held constant is because the facility is currently certified for 16 in-center stations and is operating at 98.4% of its station capacity. Due to physical constraints in the building housing the facility the building cannot accommodate any additional in-center stations. The applicant states that “*more patients would require more stations that the facility does not have the capacity to add.*”
- The applicant does not project growth for its IC patients who do not reside in Edgecombe County.
- Projected utilization of 3.94 in-center patients per station per week at the end of OY1 meets the minimum of 2.8 patients per station per week required by 10A NCAC 14C .2203(b).

### **Access to Medically Underserved Groups**

In Section C, page 31, the applicant states:

*“The applicant and its parent organization, Fresenius Medical Care, has a long history of providing dialysis services to the underserved populations of North Carolina. ... Fresenius Medical Care operates more than 100 dialysis facilities across North Carolina. Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.*

*It is our 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 for each medically underserved group, as shown in the following table.

<b>Group</b>	<b>Estimated Percentage of Total Patients during the Second Full Fiscal Year</b>
Low-income persons	91.7%
Racial and ethnic minorities	81.7%
Women	46.7%
Persons with Disabilities	50.0%
Persons 65 and older	16.7%
Medicare beneficiaries	80.0%
Medicaid recipients	91.7%

Source: Section C, page 31

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 providing services to all patients referred for ESRD services.
- Fresenius' facilities have historically provided care to all in need of ESRD services, including underserved persons.

### **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 service, eliminate a service, or relocate a facility or services. Therefore, Criterion (3a) is not applicable to this review.

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

**CA**

The applicant proposes to add no more than one in-center dialysis station to FMC Tarboro pursuant to Condition 2 of the facility need methodology for a total of no more than 16 stations upon completion of this project and Project ID# L-12696-25 (relocate 1 station from FMC Tarboro).

In Section E, page 38, the applicant states that there were no alternatives to consider because:

- The applicant states that failure to apply for an additional station at FMC Tarboro would result in higher utilization rates.
- The applicant states that failure to apply for additional stations leads to higher utilization rates, potentially interrupts patient admissions to the facility, potentially requires an evening shift which may not be convenient or accessible for the patients and would thus be the least 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 applicant's proposal is in response to a facility need pursuant to Condition 2 of the facility need methodology, as reported in the 2025 SMFP, Table 9D, page 137.
- 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 2025 SMFP, the certificate holder shall develop no more than one additional in-center dialysis station at FMC Tarboro for a total of no more than 16 stations at upon completion of this project and Project ID# L-12696-25 (relocate 1 station from FMC Tarboro).**
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 October 1, 2026.**

4. **The certificate holder shall develop and implement strategies to provide culturally competent services to members of its defined medically underserved community that are consistent with representations made in the certificate of need application.**
  5. **The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

**C**

The applicant proposes to add no more than one in-center dialysis station to FMC Tarboro pursuant to Condition 2 of the facility need methodology for a total of no more than 16 stations upon completion of this project and Project ID# L-12696-25 (relocate 1 station from FMC Tarboro).

**Capital and Working Capital Costs**

In Section F, pages 40-41, the applicant states the proposed project does not require any capital or working capital because the existing facility is operational and has the space required for the proposed additional station.

**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, the applicant projects that revenues will exceed operating expenses in the first two operating years following completion of the project, as shown in the table below.

	<b>1<sup>st</sup> Full Fiscal Year (CY2027)</b>	<b>2<sup>nd</sup> Full Fiscal Year (CY2028)</b>
Total Treatments	<b>9,324</b>	<b>9,324</b>
Total Gross Revenues (Charges)	\$58,657,284	\$58,657,284
Total Net Revenue	\$2,961,573	\$2,961,573
Average Net Revenue per Treatment	\$318	\$318
Total Operating Expenses (Costs)	\$2,450,292	\$2,471,014
Average Operating Expense per Treatment	\$263	\$265
Net Income	<b>\$511,282</b>	<b>\$490,559</b>

Source: Form F.2, page 83.

The assumptions used by the applicant in preparation of the pro forma financial statements are provided immediately following Form F.2 and in Forms F.3 and F.4 in Section Q. The

applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following reasons:

- The applicant adequately explains the assumptions used to project revenue, such as projected reimbursement rates, and operating costs, such as salaries.
- Charges and expenses are based on historical facility operations projected forward.
- Payor percentages are based on historical facility operations.
- FTEs and salaries are based on current staffing and projected to average annual salary increases of 2.0%.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions
- The applicant adequately demonstrates the availability of 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 charges

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

### **C**

The applicant proposes to add no more than one in-center dialysis station to FMC Tarboro pursuant to Condition 2 of the facility need methodology for a total of no more than 16 stations upon completion of this project and Project ID# L-12696-25 (relocate 1 station from FMC Tarboro).

On page 113, the 2025 SMFP defines the service area for dialysis stations as “*the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” FMC Tarboro is in Edgecombe County. Thus, the service area for this facility consists of Edgecombe County. Facilities may also serve residents of counties not included in their service area.

According to Table 9A of the 2025 SMFP, there are three existing or approved dialysis facilities in Edgecombe County, all of which are owned and operated by Fresenius. Information on these dialysis facilities, from Table 9A of the 2025 SMFP, is provided below:

<b>Edgecombe County Dialysis Facilities Certified Stations and Utilization as of December 31, 2023</b>				
<b>Dialysis Facility</b>	<b>Owner</b>	<b>Location</b>	<b># of Certified Stations</b>	<b>Utilization</b>
BMA East Rocky Mount	Fresenius	Rocky Mount	30	85.83%
Fresenius Medical Clinic Tarboro	Fresenius	Tarboro	15	100.0%
Fresenius Kidney Care Boice-Willis	Fresenius	Rocky Mount	16	73.44%
Dialysis Care of Edgecombe County*	DaVita	Tarboro	Facility Closed	

Source: 2025 SMFP, Chapter 9, Table 9A, page 122.

\*Facility closed as of February 11, 2024.

In Section G, pages 45-46, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Edgecombe County. The applicant states:

*“The applicant proposes to develop one dialysis station at an existing facility pursuant to Condition 2 of the Facility Need Methodology in the 2025 SMFP. The need addressed by this application is not specific to Edgecombe County as a whole. The station is needed by the patient population projected to be served by the FMC Tarboro facility. The projections for future patient populations to be served begin with the patient population at the facility as of December 31, 2024. The applicant is not projected to serve patients currently being served in another facility or served by another provider. These stations are needed to support the growing patient census at the FMC Tarboro facility.*

*The station proposed in this application is a backfill of one station pursuant to CON Project ID# L-12969-25 that is under review. BMA does not believe adding one station will duplicate any services because approval of this application will net 16 stations, which is the total number of stations the facility is already certified for.”*

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 station is needed in addition to the existing or approved dialysis station in the service area.
- There is a facility need determination in the 2025 SMFP, Table 9D, page 137, for six dialysis stations at FMC Tarboro.

**Conclusion**

The Agency reviewed the:

- Application

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

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

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

**C**

The applicant proposes to add no more than one in-center dialysis station to FMC Tarboro pursuant to Condition 2 of the facility need methodology for a total of no more than 16 stations upon completion of this project and Project ID# L-12696-25 (relocate 1 station from FMC Tarboro).

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

<b>POSITION</b>	<b>Current FTE Positions (7/18/2025)</b>	<b>FTE POSITIONS OY1 (CY2027)</b>	<b>FTE POSITIONS OY2 (CY2028)</b>
Administrator	1.00	1.00	1.00
RN	1.00	1.00	1.00
Patient Care Technician (PCT)	7.00	7.00	7.00
Dietician	0.50	0.50	0.50
Social Worker	0.50	0.50	0.50
Maintenance	1.00	1.00	1.00
Administration/Clerical	1.00	1.00	1.00
FMC Director Operations	0.09	0.09	0.09
FMC Chief Technician	0.09	0.09	0.09
FMC In-Service	0.12	0.12	0.12
<b>Total</b>	<b>12.30</b>	<b>12.30</b>	<b>12.30</b>

Source: Section Q Form H, page 92.

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.2 and H.3, pages 47-48, 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 all the reasons described above.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

### **C**

The applicant proposes to add no more than one in-center dialysis station to FMC Tarboro pursuant to Condition 2 of the facility need methodology for a total of no more than 16 stations upon completion of this project and Project ID# L-12696-25 (relocate 1 station from FMC Tarboro).

### **Ancillary and Support Services**

In Section I, page 49, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 49-54, the applicant explains how each ancillary and support service is or will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant currently provides dialysis services at FMC Tarboro with the necessary ancillary and support services
- The applicant states that it has agreements in place for lab services, hospital affiliation, and transplant services

### **Coordination**

In Section I, page 54, 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 the following:

- The applicant discusses its 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 for all the reasons described above.

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

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

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

NA

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

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

NA

The applicant 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 61, the applicant provides the historical payor mix during CY 2024 for the proposed services, as shown in the table below.

<b>FMC Tarboro IC Patients Historical Payor Mix CY 2024</b>	
<b>Primary Payor Source at Admissions</b>	<b>% of Total Patients</b>
Self-Pay	4.27%
Insurance*	4.10%
Medicare*	86.83%
Medicaid*	0.89%
Other	3.90%
<b>Total</b>	<b>100.0%</b>

Source: Section L, page 61.

\*Including any managed care plans

In Section L, page 63, the applicant provides the following comparison.

	<b>Percentage of Total Patients Served by the Facility or Campus during the Last Full FY2024</b>	<b>Percentage of the Population of the Service Area</b>
Female	46.7%	53.4%
Male	53.3%	46.6%
Unknown	na	na
64 and Younger	83.3%	78.5%
65 and Older	16.7%	21.5%
American Indian	na	0.8%
Asian	na	0.5%
Black or African American	78.3%	57.4%
Native Hawaiian or Pacific Islander	na	0.2%
White or Caucasian	21.7%	39.3%
Other Race	na	8.0%
Declined / Unavailable	na	na

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 64, the applicant states it has no such obligation.

In Section L, page 64, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights equal access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity 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 64, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation (CY2028) following completion of the project, as shown in the table below.

<b>FMC Tarboro IC Patients Projected Payor Mix CY 2028</b>	
<b>Primary Payor Source at Admissions</b>	<b>% of Total Patients</b>
Self-Pay	4.27%
Insurance*	4.10%
Medicare*	86.83%
Medicaid*	0.89%
Other: Misc. Incl. VA	3.90%
<b>Total</b>	<b>100.00%</b>

Source: Section L, page 64.

\*Including any managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 4.27% of in-center services will be provided to self-pay patients, 86.83% to Medicare patients and 0.89% to Medicaid patients.

On pages 64-65, 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 reasons:

- The projected payor mix is based on the historical treatment volumes at FMC Tarboro.
- Projections assume that there will be no changes to the payor mix as a result of this project.

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.5, page 66, 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 one in-center dialysis station to FMC Tarboro pursuant to Condition 2 of the facility need methodology for a total of no more than 16 stations upon completion of this project and Project ID# L-12696-25 (relocate 1 station from FMC Tarboro).

In Section M, page 67, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-2. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- The applicant provides a copy of a letter sent to Edgecombe Community College offering the facility as a training site for nursing students.
- The applicant states it often receives requests for information from program directors and individual students, and, in response, the Center Manager discusses dialysis and ESRD for students and offers access to the patients and facility.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

## C

The applicant proposes to add no more than one in-center dialysis station to FMC Tarboro pursuant to Condition 2 of the facility need methodology for a total of no more than 16 stations upon completion of this project and Project ID# L-12696-25 (relocate 1 station from FMC Tarboro).

On page 113, the 2025 SMFP defines the service area for dialysis stations as “*the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” FMC Tarboro is in Edgecombe County. Thus, the service area for this facility consists of Edgecombe County. Facilities may also serve residents of counties not included in their service area.

According to Table 9A of the 2025 SMFP, there are three existing or approved dialysis facilities in Edgecombe County, all of which are owned and operated by Fresenius. Information on these dialysis facilities, from Table 9A of the 2025 SMFP, is provided below:

<b>Edgecombe County Dialysis Facilities Certified Stations and Utilization as of December 31, 2023</b>				
<b>Dialysis Facility</b>	<b>Owner</b>	<b>Location</b>	<b># of Certified Stations</b>	<b>Utilization</b>
BMA East Rocky Mount	Fresenius	Rocky Mount	30	85.83%
Fresenius Medical Clinic Tarboro	Fresenius	Tarboro	15	100.0%
Fresenius Kidney Care Boice-Willis	Fresenius	Rocky Mount	16	73.44%
Dialysis Care of Edgecombe County*	DaVita	Tarboro	Facility Closed	

Source: 2025 SMFP, Chapter 9, Table 9A, page 122.

\*Facility closed as of February 11, 2024.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 68, the applicant states:

*“The applicant does not expect this proposal to have any effect on the competitive climate in Edgecombe County. The applicant is not projected to serve patients currently being served in another facility or by another provider...”*

*“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 Tarboro.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 69, the applicant states:

*“The applicant is serving a significant number of dialysis patients residing in the area of the facility. Approval of this application will allow the facility to continue serving patients who reside in the area. Consequently, these patients will have a shorter commute to and from dialysis treatment.”*

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

Regarding the impact of the proposal on quality, in Section N, page 69, 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. ...*

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

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 69, 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 ad services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or any other grouping /category or basis for being an underserved person."*

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

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

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

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

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

### **C**

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 a total of 129 of this type of facility located in North Carolina.

In Section O, page 74, the applicant states that during the 18 months immediately preceding the submittal of the application, incidents related to immediate jeopardy had not occurred in any of the Fresenius Medical Care related facilities in North Carolina. After reviewing and considering information provided by the applicant, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

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

## C

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

### 10A NCAC 14C .2203 PERFORMANCE STANDARDS

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

**-NA-** FMC Tarboro 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 in Section Q Form C Utilization, the applicant projects that FMC Tarboro will serve 63 in-center patients on 18 stations, a utilization rate of 3.94 (63 patients / 16 stations = 3.94) patients per station per week, as of the end of the first

operating year (CY2027) following project completion, meeting the 2.8 IC patients per station per week required by this Rule. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

- (c) *An applicant proposing to establish a new dialysis facility dedicated to home hemodialysis or peritoneal dialysis training shall document the need for the total number of home hemodialysis stations in the facility based on training six home hemodialysis patients per station per year as of the end of the first full fiscal year of operation following certification of the facility.*
- NA- The applicant does not propose establishing a new dialysis facility dedicated to home hemodialysis or peritoneal dialysis and does not plan to begin offering those services in this application. Therefore, this Rule does not apply.
- (d) *An applicant proposing to increase the number of home hemodialysis stations in a dialysis facility dedicated to home hemodialysis or peritoneal dialysis training shall document the need for the total number of home hemodialysis stations in the facility based on training six home hemodialysis patients per station per year as of the end of the first full fiscal year of operation following certification of the additional stations.*
- NA- The applicant does not propose to increase the number of home hemodialysis stations or peritoneal dialysis stations and does not plan to begin offering those services in this application. Therefore, this Rule does not apply.
- (e) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section C.3, pages 26-27, and the Form C Utilization subsection of Section Q, pages 77-79, 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.