

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: September 12, 2025

Findings Date: September 12, 2025

Project Analyst: Crystal Kearney

Co-Signer: Gloria C. Hale

Project ID #: J-12667-25

Facility: Fresenius Medical Care Eastern Wake

FID #: 061335

County: Wake

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

Project: Add no more than seven in-center dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 22 in-center dialysis stations upon project completion

REVIEW CRITERIA

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

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

C

Bio-Medical Applications of North Carolina, Inc. (hereinafter referred to as “BMA” or the “applicant”) proposes to add no more than seven dialysis stations at Fresenius Medical Care Eastern Wake (hereinafter referred to as “FMC Eastern Wake”) pursuant to Condition 2 of the facility need methodology for a total of no more than 22 stations upon project completion.

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 9B on page 135 of the 2025 SMFP, the county need methodology shows there is not a county need determination for additional dialysis stations in Wake 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 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 in Table 9A, page 129 of the 2025 SMFP, is 90.0% or 3.6 patients per station per week, based on 54 in-center dialysis patients and 15 certified dialysis stations (54 patients / 15 stations = 3.6, $3.6/4=90.0\%$).

As shown in Table 9D, on page 138 of the 2025 SMFP, based on the facility need methodology for dialysis stations, the potential number of stations needed is up to seven additional stations; thus, the applicant is eligible to apply to add up to seven stations during the 2025 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

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

Policies

One policy in Chapter 4 of the 2025 SMFP 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. ”*

Demographics

In Section B, page 21, the applicant provided the following table that reflects the patient demographics at FMC Eastern Wake.

FMC Eastern Wake Last Full FY before Submission of the Application		
Group	% of Total Patients Served	% of the Population of the Service Area
Low-income persons	19	33.3%
Racial and ethnic minorities	40	70.2%
Women	27	47.4%
Handicapped persons	12	21.1%
The Elderly	31	54.4%
Medicare beneficiaries	42	73.7%
Medicaid beneficiaries	19	33.3%
American Indian	0	0
Asian	1	1.8%
Black or African American	34	59.6%
Native Hawaiian or Pacific Islander	0	0
White or Caucasian	20	35.1%
Other Race	2	3.5%
Declined/Unavailable	0	0

Note: Other races include Hispanic, Latino, or two or more races

Source: Section B, page 21 of the application

Strategies to Provide Culturally Competent Services

In Section B, pages 21-24, the applicant adequately describes the strategies it would implement to provide culturally competent services to members of the medically underserved community it identified in the table above and how progress will be assessed. The information provided by the applicant is reasonable and supports the determination that the applicant's proposal will provide culturally competent 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 based on the following:

- The applicant does not propose to develop more dialysis stations than are determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with *Policy GEN-5* based on the following:
 - The applicant provided patient demographics for Wake County.
 - The applicant described how its strategies reflect cultural competence because the plan meets patients where they are and individualizes their care and it helps teammates develop a set of skills and knowledge to better understand the importance of respecting patients' different perspectives.
 - The applicant described how it will measure and periodically assess increased equitable access to healthcare services and reduction in health disparities including assessing data and performance for different patient populations and reviewing the data and plan annually.

(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 seven in-center dialysis stations at FMC Eastern Wake pursuant to Condition 2 of the facility need methodology for a total of no more than 22 dialysis stations upon project completion.

Patient Origin

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

The following tables illustrate historical and projected patient origin.

FMC Eastern Wake				
County	Historical CY 2024		Second Full FY of Operation following Project Completion CY 2029	
	# of in-center Patients	% of Total	# of in-center Patients	% of Total
Wake	47.0	78.3%	73.3	88.2%
Franklin	8.0	13.3%	8.0	10.5%
Nash	1.0	1.7%	1.0	1.3%
Virginia	1.0	1.7%	0	0
Other States	3.0	5.0%	0	0
Total	60.0	100.0%	82.3	100.0%

Source: Section C, pages 25 and 26

In Section C, pages 26-27, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported based on the following:

- The applicant began projections for patient utilization with the patient population at FMC Eastern Wake as of December 31, 2024. The facility had 60 patients and 47 of those patients lived in the Wake County service area. The remaining 13 patients lived outside the service area.
- The applicant used half the Average Annual Change Rate for the Past Five Years (5-Year AACR) of 9.3% for the in-center patients living in Wake County. The period of growth begins January 1, 2025, and is calculated forward to December 31, 2029.
- The applicant did not calculate growth for the patients living outside of Wake County and included only Franklin and Nash County patients as those counties are contiguous.

Analysis of Need

In Section C, pages 29-30, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 30, 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 [sic] for the proposed project. The applicant has identified the population to be served as 76.1 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 86.45%, or 3.46 patients per station per week 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 facility. The additional stations are needed to meet the growing demand for dialysis at the facility and to ensure adequate access to the population to be served identified in this application.”

The information is reasonable and adequately supported because 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. The discussion regarding the need methodology found in Criterion (1) is incorporated herein by reference.

Projected Utilization

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

Form C Utilization	Last Full FY CY 2024	Interim Full FY CY 2025	Interim Full FY CY 2026	Interim Full FY CY 2027	1 st Full FY CY 2028	2 nd Full FY CY 2029
In-Center Patients						
# of Patients at the Beginning of the Year	54	60	60	65	70	76
# of Patients at the End of the Year	60	60	65	70	76	82
Average # of Patients during the Year	57	60	63	68	73	79
# of Treatments / Patients / Year	148	148	148	148	148	148
Total # of Treatments	7,916	8,907	9,288	10,028	10,837	11,721

In Section Q immediately following Form C, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

In Center Assumptions:

1. The 2025 SMFP, Table 9D: Dialysis Station Need Determination by Facility, indicates that FMC Eastern Wake qualifies to apply for up to seven additional dialysis stations pursuant to Condition 2 of the Facility Need Methodology. This is an application for seven additional dialysis stations.
2. The application begins projections of the future patient population to be served, with the facility census as of December 31, 2024. This information was reported on the 2024 ESRD Data Collection Form submitted to DHSR Healthcare Planning in February 2025 and will be available to the CON Project Analyst during this review.
3. The Five Year Average Annual Change Rate (5-Year AACR) for Wake County in the 2025 SMFP is 0.9%. While this rate is commonly used to project growth for future ESRD patient populations, an applicant is not limited to only using this rate. The tables below detail the facility's total in-center patient census and their Wake County in-center patient census for the past five years. This information is taken from the 2022-2025 SMFP and the 2024 ESRD Data Collection Form submitted to DHSR Healthcare Planning in February 2025.

FMC Eastern Wake						
	Dec. 31, 2020	Dec. 31, 2021	Dec. 31, 2022	Dec. 31, 2023	Dec. 31, 2024	5 -Year AACR
Total ICHD Patients	27	43	47	54	60	
% Growth		59.3%	9.3%	14.9%	11.1%	23.6%

ICHD-in-center hemodialysis Source: Section Q of the application page 80

FMC Eastern Wake						
	Dec. 31, 2020	Dec. 31, 2021	Dec. 31, 2022	Dec. 31, 2023	Dec. 31, 2024	5 -Year AACR
Wake County ICHD Patients	25	38	39	45	47	
% Growth		52.0%	2.6%	15.4%	4.4%	18.6%

ICHD-in-center hemodialysis Source: Section Q of the application page 80

The applicant will project growth of the Wake County in-center patient population using a growth rate commensurate with the facility's historical experience. The applicant will project growth of the Wake County in-center patient population using a 9.3% growth rate which is one half of the facility's 5-Year AACR of 18.6% for Wake County ICHD patients, shown in the table above. The applicant believes this growth rate is both reasonable and conservative given the growth in the total ICHD patient population (23.6%) and the Wake County ICHD patient population (18.6%) over the last five years.

4. As of December 31, 2024, the facility was serving a total of nine in-center patients from Franklin and Nash County. Franklin and Nash County are both contiguous to Wake County, thus it is reasonable to conclude that these patients will continue dialysis at this facility as a function of patient choice. The applicant will not project growth in this segment of the patient population, but these patients will be added to future projections at the appropriate points of time.
5. The stations proposed in this application are projected to be certified on December 31, 2027.

Operating Year 1 is the period from January 1- December 31, 2028

Operating Year 2 is the period from January 1- December 31, 2029

In-Center Methodology:

Begin with the Wake County patient population as of December 31, 2024	47.0
Project the Wake County population forward for one year to December 31, 2025, using one-half of the facility's 5-year historical growth rate for Wake County patients.	$47.0 \times 1.093 = 51.4$
Add the patients from other counties. This is the projected ending census for Interim Year 1.	$51.4 + 9.0 = 60.4$
Project the Wake County patient population forward for one year to December 31, 2026, using one-half of the facility's 5-year historical growth rate for Wake County patients.	$51.4 \times 1.093 = 56.1$
Add the patients from other counties. This is the projected ending census for Interim Year 2.	$56.1 + 9.0 = 65.1$
Project the Wake County patient population forward for one year to December 31, 2027, using one-half of the facility's 5-year historical growth rate for Wake County patients.	$56.1 \times 1.093 = 61.4$
Add the patients from other counties. This is the projected ending census for Interim Year 3.	$61.4 + 9.0 = 70.4$
Project the Wake County patient population forward for one year to December 31, 2028, using one-half of the facility's 5-year historical growth rate for Wake County patients.	$61.4 \times 1.093 = 67.1$
Add the patients from other counties. This is the projected ending census for Operating Year 1.	$67.1 + 9.0 = 76.1$
Project the Wake County patient population forward for one year to December 31, 2029, using one-half of the facility's 5-year historical growth rate for Wake County patients.	$67.1 \times 1.093 = 73.3$
Add the patients from other counties. This is the projected ending census for Operating Year 2.	$73.3 + 9.0 = 82.3$

Source: Section Q, page 81

	Operating Year 1	Operating Year 2
In-center	76.1	82.3

Source: Section Q, page 82

- At the end of FY1, FMC Eastern Wake is projected to serve 76 in-center patients and at the end of FY2, the facility is projected to serve 82 in-center patients.
- The applicant projects to serve 76 patients on 22 stations, which is 3.45 patients per station per week ($76 \text{ patients} / 22 \text{ stations} = 3.45$), by the end of FY1.
- This meets the minimum requirements of 3.45 patients per station per week as of the end of the first full fiscal year as required by 10 A NCAC 14C .2203(b).

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

- The applicant projects future utilization based on historical utilization and growth.

- Projected utilization at the end of FY1 meets the minimum 3.45 patients per station per week as required by 10A NCAC 14C .2203(b).

Access to Medically Underserved Groups

In Section C, page 32, the applicant states :

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

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Group	Percentage of Total Patients during the Second Full Fiscal Year
Low income persons	33.3%
Racial and ethnic minorities	70.2%
Women	47.4%
Persons with Disabilities	21.1%
Persons 65 and older	54.4%
Medicare beneficiaries	73.7%
Medicaid recipients	33.3%

Source: Section C, page 32

Note: Not all patients who are low-income qualify for Medicaid

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 applicant’s history of providing services to medically underserved groups.

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.

- (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.

NC

The applicant proposes to add no more than seven in-center dialysis stations at FMC Eastern Wake pursuant to Condition 2 of the facility need methodology for a total of no more than 22 dialysis stations upon project completion.

In Section E, page 39, 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 at FMC Eastern Wake would result in higher utilization. Therefore, this was a less effective alternative.
- Apply for fewer stations - the applicant states this alternative would fail to recognize the patient population choosing to dialyze at FMC Eastern Wake and would result in some patients not being able to receive dialysis there.
- 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.

In Section C, page 39, the applicant states that its proposal is the most effective alternative because the additional stations will increase capacity and proactively address the issues of growth and access at FMC Eastern Wake and provide opportunities to open appointment times on the more desirable first shift.

However, the applicant does not adequately demonstrate that the alternative proposed in this application is the most effective alternative to meet the need based on the following:

- The applicant did not demonstrate that its projected staffing was sufficient to meet its projected need. The discussion regarding availability of resources for the proposed project, including health manpower and management personnel, found in Criterion (7) is incorporated herein by reference.
- The applicant did not demonstrate that its proposed project was financially feasible since financial feasibility is based, in part, on the reasonableness of projected costs. The discussion regarding financial feasibility found in Criterion (5) is incorporated herein by reference.

- Because the applicant did not demonstrate the financial feasibility of the proposed project, the applicant cannot demonstrate that any enhanced competition in the service area includes a positive impact on the cost-effectiveness of the proposed project. The discussion regarding the proposed project's effect on competition, found in Criterion (18a) 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 not conforming to this criterion for all the reasons stated above.

- (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.

NC

The applicant proposes to add no more than seven in-center dialysis stations at FMC Eastern Wake pursuant to Condition 2 of the facility need methodology for a total of no more than 22 dialysis stations upon project completion.

Capital and Working Capital Costs

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

Construction Costs	\$1,890,382
Architect/Engineering Fees	\$169,071
Non-Medical Equipment	\$263,670
Furniture	\$34,813
Contingency	\$295,333
Total Capital Cost	\$2,653,269

In Section Q, page 85, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions because Fresenius Real Estate and Construction Services (RECS) team used estimates based upon a national database used by the RECS team to develop the capital cost for the proposed project.

In Section F, page 42, the applicant states that there will be no start-up costs or initial operating expenses because FMC Eastern Wake is an existing facility.

Availability of Funds

In Section F, page 40, the applicant states that the capital cost will be funded with Fresenius Medical Care Holdings, Inc.'s accumulated reserves.

Exhibit F-2 contains a letter dated July 15, 2025, and signed by the VP Corporate Tax North America for Fresenius Medical Care Holdings, Inc., which commits to funding the capital cost for the project from accumulated reserves. The applicant states in the letter that the 2024 Consolidated Balance Sheet reflects more than \$197 million in cash and total assets exceeding \$25 billion.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project because a Fresenius Medical Care Holdings, Inc. official confirms the availability of the funding proposed for the capital needs of the project and commitment to use those funds to develop the proposed project.

Financial Feasibility

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

FMC Eastern Wake	1st Full FY CY 2028	2nd Full FY CY 2029
Total # Treatments	10,837	11,721
Total Gross Revenues (Charges)	\$68,176,554	\$73,737,670
Total Net Revenue	\$3,084,969	\$3,336,608
Average Net Revenue per Treatment	\$285	\$285
Total Operating Expenses (Costs)	\$3,189,692	\$3,305,448
Average Operating Expense per Treatment	\$294	\$282
Net Income	\$(104,723)	\$31,161

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q. However, the applicant does not adequately demonstrate that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- Projected operating expenses are questionable because the applicant did not adequately discuss why its projected staffing was reasonable given the increase of over 20 patients by CY2029. Since the level of staffing was questionable, which necessarily affects operating costs, it in turn makes the financial feasibility of the project questionable. The discussion regarding the availability of resources for the proposed project, including health manpower and management personnel, found in Criterion (7) 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 not conforming to this criterion for the following reasons:

- The applicant does not adequately demonstrate that the capital and working capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
 - The applicant does not adequately demonstrate availability of sufficient funds for the capital and working capital needs of the proposal for all the reasons described above.
 - The applicant does not adequately demonstrate sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to add no more than seven in-center dialysis stations at FMC Eastern Wake pursuant to Condition 2 of the facility need methodology for a total of no more than 22 dialysis stations upon project completion.

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

According to the proposed 2026 SMFP, Table 9A, pages 119-120, there are twenty-one existing or approved dialysis facilities in Wake County, as shown in the following table:

FMC Eastern Wake	Certified Stations as of 12/31/2024	# of In-center Patients as of 12/31/2024	Utilization by % as of 12/31/2024	# of additional stations approved
BMA Fuquay Varina	29	93	80.17%	1
BMA of Raleigh Dialysis	50	120	60.00%	0
Cary Kidney Center	29	84	72.41%	0
Downtown Raleigh Dialysis	0	18	0.00%	0
FMC Eastern Wake	15	60	100.00%	9
FMC Morrisville	13	45	86.54%	5
FMC New Hope Dialysis	36	116	80.56%	8
FMC Northern Wake	20	57	71.25%	0
FMC Wake Dialysis Clinic	50	150	75.00%	0
FKC Holly Springs	10	36	90.00%	12
FKC Knightdale	0	0	0.00%	0
FMC Apex	20	66	82.50%	4
FMC Central Raleigh	19	50	65.79%	0
FMC Millbrook	17	63	92.65%	7
FMC Rock Quarry	0	0	0.00%	0
FMC White Oak	20	72	90.00%	5
Oak City Dialysis	32	78	60.94%	0
Southwest Wake County Dialysis	30	105	87.50%	3
Tarheel Place Dialysis	0	0	0.00%	0
Wake Forest Dialysis Center	21	81	96.43%	10
Zebulon Kidney Center	30	79	65.83%	0
Total	441	1,373	77.84%	172

Source: Table 9A, proposed 2026 SMFP, page 119-120

In Section G, page 47, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Wake County. The applicant states:

- The applicant states that the stations are needed by the patient population projected to be served by the FMC Eastern Wake facility.
- The applicant states that the projections for future patient populations to be served begin with the patient population at the facility as of December 31, 2024, and a conservative increase of the Wake County patients at a rate of 9.3%, which is less than the facility's total 5-Year AACR ICHD patient census and less than the facility's Wake County 5-Year AACR ICHD patient census.
- The applicant states that the applicant is not projected to serve patients currently being served in another facility or served by another provider.
- The applicant states that while the county inventory of stations increase as a result of this project, the stations requested in this application are needed as identified in the 2025 SMFP and will increase capacity at an existing facility that was operating at 100% utilization as of December 31, 2024.

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:

- There is a facility need determination in the 2025 SMFP for up to seven dialysis stations at FMC Eastern Wake.
- The applicant adequately demonstrates that the proposed dialysis stations are needed in addition to the existing or approved dialysis stations in Wake County.

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.

- (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.

NC

The applicant proposes to add no more than seven in-center dialysis stations at FMC Eastern Wake pursuant to Condition 2 of the facility need methodology for a total of no more than 22 dialysis stations upon project completion.

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

Position	Current FTE Staff	Projected FTE Staff
	<i>As of 4/16/2025</i>	2nd Full Fiscal Year CY 2029
Administrator (FMC Clinical Manager)	1.00	1.00
Registered Nurses (RNs)	2.00	2.00
Technicians (PCT)	7.00	7.00
Medical Records	1.00	1.00
Dietician	1.00	1.00
Social Worker	1.00	1.00
Maintenance	1.00	1.00
Other - (FMC Director of Operations)	0.13	0.13
Other – (FMC Chief Technician)	0.13	0.13
Other (FMC In-Service)	0.10	0.10
TOTAL	14.36	14.36

The assumptions and methodology used to project staffing are provided in Section Q, page 97. In Section H, pages 48-49, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

However, the applicant does not adequately demonstrate the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant is proposing to add seven dialysis stations to a facility with 15 dialysis stations for a total of 22 dialysis stations. The applicant served 60 patients at the end of CY2024 and is proposing to serve 82.3 patients in CY2029, which is an increase of over 20 patients. However, despite this increase, the projected staffing FTEs remain the same in the 2nd full fiscal year of the project as current staffing. The applicant does not provide adequate information to determine whether projected staffing is sufficient to provide the proposed services due to the projected increase in patients and utilization. Therefore, the availability of staffing for the provision of services proposed to be provided is questionable and is not reasonable or adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is not 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 seven in-center dialysis stations at FMC Eastern Wake pursuant to Condition 2 of the facility need methodology for a total of no more than 22 dialysis stations upon project completion.

Ancillary and Support Services

In Section I, page 50, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 50-51, the applicant explains how each ancillary and support service is or will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available.

Coordination

In Section I, page 55, 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 its established relationships with other healthcare providers and social services agencies in Wake County.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

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

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

NA

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

- (11) Repealed effective July 1, 1987.

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

C

The applicant proposes to add no more than seven in-center dialysis stations at FMC Eastern Wake pursuant to Condition 2 of the facility need methodology for a total of no more than 22 dialysis stations upon project completion.

In Section K, page 58, the applicant states that the project involves constructing 2,000 square feet of additional space to expand the existing space. Exhibit K-2 includes a line drawing of the facility and a schematic of the new addition to the building.

In Section K, pages 58-59, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following:

- The applicant states that no renovation is required.
- The applicant states that the new dialysis stations will be installed in a brick-and-mortar expansion to the existing building to develop the new stations.
- The applicant states that the FMC Real Estate and Construction Services department has extensive experience designing dialysis facilities.
- The applicant states that the corporate design teams utilize cost savings measures within each facility design, and facilities are designed to ensure a safe and orderly flow of patients and staff within the facility.
- The applicant states that Fresenius Medical Care is committed to ensuring the building will maximize improved energy efficiency.
- The applicant states that the facility plumbing systems have been designed to ensure conservation of water.
- The applicant states that the FMC building specifications require the exterior building envelope (consisting of roofing, wall, and glass system) meets current requirements for energy conservation.

In Section K, page 59, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the following:

- The applicant states that adding seven dialysis stations to this facility will ensure continued convenient access to care for the patients of the area.
- The applicant states that the costs of adding stations are not passed on to the patient.
- The applicant states that the project will not increase costs or charges to the public for the proposed services.

In Section K, pages 59-60, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit K-2.

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.

- (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 62, the applicant provides the historical payor mix during CY 2024 for the proposed services, as shown in the table below.

FMC Eastern Wake CY 2024		
Payor Source	In-Center Dialysis	
	# of Patients	% of Total
Self-Pay	3.5	5.8%
Insurance*	6.3	10.6%
Medicare*	5.3	8.9%
Medicaid*	43.0	71.7%
Other	1.8	3.0%
Total	60.0	100.0%

Source: Section L, page 62

*Including any managed care plans

In Section L, page 64, the applicant provides the following comparison.

FMC Eastern Wake	Last Full FY before Submission of the Application	
	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	47.4%	51.0%
Male	52.6%	49.0%
Unknown	0.0%	0.0%
64 and Younger	45.6%	86.6%
65 and Older	54.4%	13.4%
American Indian	0.0%	0.8%
Asian	1.8%	9.4%
Black or African-American	59.6%	20.6%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	35.1%	66.3%
Other Race	3.5%	14.4%
Declined/ Unavailable	0.0%	0.0%

Source: Section L, page 64

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 65, the applicant states that the facility is not obligated to provide uncompensated care, community service or access by minorities and persons with disabilities.

In Section L, page 65, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against FMC Eastern Wake.

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 65, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

Carthage Dialysis Projected Payor Mix during the 2nd Full FY CY 2029		
Payor Source	In-Center Dialysis	
	# of Patients	% of Total
Self-Pay	4.8	5.8%
Insurance	8.7	10.6%
Medicare	7.3	8.9%
Medicaid	59.0	71.7%
Other	2.5	3.0%
Total	82.3	100.0%

Source: Section L, page 65.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 5.8% of total services will be provided to self-pay patients, 8.9% to Medicare patients and 71.7% to Medicaid patients.

On page 66, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical payor mix at FMC Eastern Wake during the last full fiscal year (CY 2024).

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 67, 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 seven in-center dialysis stations at FMC Eastern Wake pursuant to Condition 2 of the facility need methodology for a total of no more than 22 dialysis stations upon project completion.

In Section M, page 69, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-2. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on a letter to Wake Tech Community College encouraging the school to include the dialysis facility in their clinical rotations for nursing students.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.

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

NC

The applicant proposes to add no more than seven in-center dialysis stations at FMC Eastern Wake pursuant to Condition 2 of the facility need methodology for a total of no more than 22 dialysis stations upon project completion.

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

According to the proposed 2026 SMFP, Table 9A, pages 119-120, there are twenty-one existing or approved dialysis facilities in Wake County, as shown in the following table:

FMC Eastern Wake	Certified Stations as of 12/31/2024	# of In-center Patients as of 12/31/2024	Utilization by % as of 12/31/2024	# of additional stations approved
BMA Fuquay Varina	29	93	80.17%	1
BMA of Raleigh Dialysis	50	120	60.00%	0
Cary Kidney Center	29	84	72.41%	0
Downtown Raleigh Dialysis	0	18	0.00%	0
FMC Eastern Wake	15	60	100.00%	9
FMC Morrisville	13	45	86.54%	5
FMC New Hope Dialysis	36	116	80.56%	8
FMC Northern Wake	20	57	71.25%	0
FMC Wake Dialysis Clinic	50	150	75.00%	0
FKC Holly Springs	10	36	90.00%	12
FKC Knightdale	0	0	0.00%	0
FMC Apex	20	66	82.50%	4
FMC Central Raleigh	19	50	65.79%	0
FMC Millbrook	17	63	92.65%	7
FMC Rock Quarry	0	0	0.00%	0
FMC White Oak	20	72	90.00%	5
Oak City Dialysis	32	78	60.94%	0
Southwest Wake County Dialysis	30	105	87.50%	3
Tarheel Place Dialysis	0	0	0.00%	0
Wake Forest Dialysis Center	21	81	96.43%	10
Zebulon Kidney Center	30	79	65.83%	0
Total	441	1,373	77.84%	172

Source: Table 9A, proposed 2026 SMFP, page 119-120

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 70, the applicant states:

“This application addresses the needs of an existing patient population that is already being served and is projected to be served by the FMC Eastern Wake dialysis facility. The additional stations being requested in this application will ensure that patients choosing to receive their treatment at this facility will continue to access to [sic] high quality dialysis care.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 71, 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 71, 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, a 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 71, 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.”

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

However, the applicant does not adequately describe the expected effects of the proposed services on competition in the service area or adequately demonstrate the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant did not adequately demonstrate that:

- 1) The proposal is cost effective because the applicant did not adequately demonstrate that projected operating costs are reasonable and therefore that the project is the least costly or most effective alternative. The discussion regarding alternatives and financial feasibility found in Criteria (4) and (5), respectively, are incorporated herein by reference. A project that cannot demonstrate the financial feasibility of the services proposed and cannot demonstrate it is the least costly or most effective alternative cannot demonstrate how enhanced competition will have a positive impact on the cost-effectiveness of the proposal.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is not 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, on 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 76, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents resulting in a finding of immediate jeopardy that occurred in any of these facilities. After reviewing and considering information provided by the applicant and considering the quality of care provided at all 129 facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

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

C

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

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 Eastern Wake 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 34, and Section Q, page 80, the applicant projects that FMC Eastern Wake will serve 76.1 in-center patients on 22 stations, or a rate of 3.46 patients per station per week ($76.1 \text{ patients} / 22 \text{ stations} = 3.46$), by 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 proposing to establish a new dialysis facility dedicated to home hemodialysis or peritoneal dialysis training shall document the need for the total number of home hemodialysis stations in the facility based on training six home hemodialysis patients per station per year as of the end of the first full fiscal year of operation following certification of the facility.*
- NA- The applicant does not propose to establish a new dialysis facility dedicated to home hemodialysis or peritoneal dialysis training. 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, pages 26-28, and Section Q, pages 80-81, 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.