

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: December 19, 2025

Findings Date: December 19, 2025

Project Analyst: Yolanda W. Jackson

Co-Signer: Gloria C. Hale

Project ID #: J-12695-25

Facility: Fresenius Kidney Care Garner Dialysis

FID #: 250853

County: Wake

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

Project: Develop a new dialysis facility by relocating no more than 7 dialysis stations from FMC White Oak and no more than 9 dialysis stations from Southwest Wake County Dialysis for a total of no more than 16 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.

NA

Bio-Medical Applications of North Carolina, Inc. (hereinafter referred to as “the applicant” or “BMA”) proposes to develop a new 16-station dialysis facility, Fresenius Kidney Care Garner Dialysis (FKC Garner Dialysis), by relocating seven dialysis stations from Fresenius Medical Care White Oak (FMC White Oak) and nine dialysis stations from Southwest Wake County Dialysis (SW Wake Dialysis). Both of the facilities from which dialysis stations will be relocated are located in Wake County. The proposed facility will offer only in-center hemodialysis upon project completion.

The applicant does not propose to:

- develop any beds or services for which there is a need determination in the 2025 SMFP
- acquire any medical equipment for which there is a need determination in the 2025 SMFP

- offer a new institutional health service for which there are any policies in the 2025 SMFP

Therefore, Criterion (1) is not applicable to this review.

- (2) Repealed effective July 1, 1987.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 develop a new 16-station dialysis facility, FKC Garner Dialysis, by relocating no more than seven dialysis stations from FMC White Oak and no more than nine dialysis stations from SW Wake Dialysis.

Patient Origin

On page 113, the 2025 SMFP defines the service area for dialysis stations as “...*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” The applicant proposes to locate the proposed dialysis facility 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.

The proposed project is for a new facility with no historical patient origin data. The following tables, from Section C, page 23, illustrates historical patient origin for calendar year (CY) 2024 for the existing dialysis stations that will be relocated from FMC White Oak and SW Wake Dialysis as part of this proposal.

County	FMC White Oak	
	Last Full FY CY2024	
	# of In-Center Patients	% of Total
Wake	68.0	94.4%
Johnston	3.0	4.2%
Other States	1.0	1.4%
Total	72.0	100.0%

County	SW Wake Dialysis	
	Last Full FY CY2024	
	# of In-Center Patients	% of Total
Wake	103.0	98.1%
Johnston	2.0	1.9%
Total	95.0 [105.0]*	100.0%

*Typographical error. Project Analyst calculation in brackets.

The following table, from Section C, page 24, illustrates projected patient origin for the proposed facility, FKC Garner Dialysis, for the second full fiscal year (FY) of operation, CY2029.

County	FKC Garner Dialysis	
	Second Full FY CY2029	
	# of In-Center Patients	% of Total
Wake	44.0	91.7%
Johnston	4.0	8.3%
Total	48.0	100.0%

In Section C, pages 24-25, the applicant provides the assumptions and methodology used to project patient origin, summarized as follows:

- In Exhibit C-3 the applicant provides 48 letters of support signed by 44 in-center patients residing in Wake County and four in-center patients residing in Johnston County. Each of the letters indicate that these patients would be willing to transfer their care to the proposed facility upon project completion.
- The applicant provides a table to illustrate the number of patients by county of patient residence and the dialysis facility where they are currently being served. All of the patients reside within the 27529 ZIP code. ZIP code 27529 is located partially in both Wake and Johnston counties.

ZIP Code: 27529			
Facility	Wake County Resident	Johnston County Resident	Totals
FMC White Oak	19	2	21
SW Wake Dialysis	13	0	13
BMA of Fuquay Varina Kidney Center	1	0	1
FMC Stallings Station	1	2	3
FKC West Johnson	10	0	10
Total	44	4	48

Source: Section C, page 24.

- The applicant projects growth of the Wake County patient population using a 0.9% growth rate in line with the 5-Year Average Annual Change Rate (AACR) for Wake County published in the 2025 SMFP.
- The applicant does not project growth of the Johnston County patient population, but these patients will be added to the future projections at specific points in time.

The applicant's assumptions are reasonable and adequately supported based on the following:

- The applicant provides patient letters of support that indicate patients residing in Wake and Johnson counties would be willing to transfer their care to the proposed facility.
- The applicant provides ZIP code information that indicates those patients who signed letters of support reside in the 27529 ZIP code and the location of the proposed facility will be in the same 27529 ZIP code.
- The applicant projects growth of the Wake County patient population based on the 5-Year AACR for Wake County published in the 2025 SMFP.

Analysis of Need

In Section C, pages 26-28, the applicant explains why it believes the population projected to utilize the proposed in-center dialysis services needs those services, summarized as follows:

- **Population Growth.** The applicant reviewed the Wake County Government Website which shows that Wake County is one of the fastest growing counties in the country and is growing by approximately 66 people per day. The applicant also reviewed U.S. Census data for April 2020-July 2023, which estimates 52% of Wake County's population growth came from people aged 55 and older. The applicant states that the 55+ segment of the population are those who will more than likely develop some form of chronic kidney disease (CKD) and end stage renal disease (ESRD) as they age and ultimately require some form of dialysis care. The applicant states that a new dialysis facility will be needed to meet the dialysis need of ESRD patients in Wake County.
- **Enhance Access to Care.** The applicant states patients with ESRD require dialysis treatments on a regular and consistent basis, typically three times per week, to maintain life. The applicant states that dialysis can be a very time-consuming and physically demanding process and 44 in-center patients who reside in Wake County and four in-center residents who reside in Johnston County have expressed an interest in transferring to the proposed facility because it is more convenient for them. The applicant states that this facility will help to improve the quality of life for ESRD patients in the area by ensuring that dialysis services are in an area convenient for the identified patient population which will improve their ability and willingness to be more compliant with their dialysis treatment.

The information is reasonable and adequately supported for all the reasons described above.

Projected Utilization

In Section Q, Form C, page 84, the applicant provides projected utilization for FKC Garner Dialysis, as illustrated in the following table.

	1st Full FY CY2028	2nd Full FY CY2029
In-Center Patients		
# of Patients at the Beginning of the Year	48	48
# of Patients at the End of the Year	48	49
Average # of Patients during the Year	48	49
# of Treatments / Patients / Year	148	148
Total # of Treatments	7,133	7,192

In Section Q, pages 85-86, the applicant provides the assumptions and methodology used to project utilization, summarized below.

- The applicant provided 48 patient letters of support in Exhibit C-3 and these letters demonstrate that 44 in-center dialysis patients reside in Wake County and four in-center dialysis patients reside in Johnston County and that they are willing to transfer their care to FKC Garner Dialysis.
- The following table identifies the 48 in-center patients by county of patient residence and dialysis facility where they are currently receiving dialysis services. All of the patients reside within the 27529 ZIP code.

ZIP Code: 27529			
Facility	Wake County Resident	Johnston County Resident	Totals
FMC White Oak	19	2	21
SW Wake Dialysis	13	0	13
BMA of Fuquay Varina Kidney Center	1	0	1
FMC Stallings Station	1	2	3
FKC West Johnson	10	0	10
Total	44	4	48

- The applicant projects growth of the Wake County patient population using a 0.9% growth rate in line with the 5-Year AACR for Wake County published in the 2025 SMFP.
- The applicant does not project growth of the Johnston County patient population, but the applicant states that these patients will be added to future projections at specific points of time.
- The relocation project is projected to be certified as of December 31, 2027.
- Operating Year (OY) 1 is the period of January 1, 2028 to December 31, 2028.

- Operating Year (OY) 2 is the period of January 1, 2029 to December 31, 2029.

The following table from Section Q, page 86, illustrates projected utilization.

The applicant begins with the 44 Wake County patients who have signed letters of support to transfer their care to the facility upon project completion on December 31, 2027.	44.0
The applicant projects the Wake County patient population forward to December 31, 2028.	$44.0 \times 1.009 = 44.4$
The applicant adds the patients from Johnston County. This is the end of Operating Year 1.	$44.4 + 4.0 = 48.4$
The applicant projects the Wake County patient population forward for one year to December 31, 2029.	$44.4 \times 1.009 = 44.8$
The applicant adds the patients from Johnston County. This is the end of Operating Year 2.	$44.8 + 4.0 = 48.8$

The applicant projects to serve 48.4 patients on 16 stations, which is 3.025 patients per station per week ($48.4 \text{ patients}/16 \text{ stations} = 3.025$), by the end of first full fiscal year of operation. The applicant projects to serve 48.8 patients on 16 stations, which is 3.03 patients per station per week ($48.8 \text{ patients}/16 \text{ stations} = 3.03$), by the end of second full fiscal year of operation. This exceeds the minimum of 2.8 patients per station per week as of the end of the first full fiscal year of operation following certification of the facility as required by 10A NCAC 14C .2203(a).

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

- The applicant’s beginning patient census is based on and supported by letters from patients currently receiving dialysis treatment at the applicant’s existing dialysis facilities who have indicated an interest in transferring to the proposed FKC Garner Dialysis facility.
- The applicant’s projected utilization in the first two years of operation is based on and supported by the 5-Year AACR for Wake County published in the 2025 SMFP.
- The applicant projects growth only in the Wake County patient population and adds patients from Johnston County after calculating the growth of Wake County patients.

Access to Medically Underserved Groups

In Section C, page 30, the applicant states,

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

services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, or health insurer.”

In Section C, page 31, the applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients during the Second Full FY
Low-income persons	28.0%
Racial and ethnic minorities	77.1%
Women	43.4%
Persons with disabilities	32.0%
Persons 65 and older	36.0%
Medicare beneficiaries	38.3%
Medicaid recipients	28.0%

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 service to all residents of the service area, including underserved groups who need dialysis 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.

- (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.

C

The applicant proposes to develop a new 16-station dialysis facility, FKC Garner Dialysis, by relocating no more than nine dialysis stations from FMC White Oak and no more than seven dialysis stations from SW Wake Dialysis.

In Section D, page 36, the applicant provides the following tables.

FMC White Oak		
County where the facility is located		Wake
1	Total number of existing, approved, and proposed dialysis stations as of the application deadline	20
2	Number of existing dialysis stations to be reduced, relocated or eliminated in this proposal	7
3	Total number of dialysis stations upon completion of this project and all other projects involving this facility	13

SW Wake Dialysis		
County where the facility is located		Wake
1	Total number of existing, approved, and proposed dialysis stations as of the application deadline	30
2	Number of existing dialysis stations to be reduced, relocated or eliminated in this proposal	9
3	Total number of dialysis stations upon completion of this project and all other projects involving this facility	21

FMC White Oak

In Section D, pages 36- 41, the applicant explains why it believes the needs of the population presently utilizing the services to be relocated will be adequately met following completion of the project. On pages 38- 39, the applicant states:

“Table 9D: Dialysis Station Need Determination by Facility in Chapter 9 of the 2025 SMFP does indicate that FMC White is eligible to apply for seven additional dialysis stations. The applicant intends to apply for seven additional stations in November 2025 to backfill the stations proposed to be relocated to the new FKC Garner Dialysis facility.

Upon completion of the proposed project and the application to backfill stations at FMC White Oak, the facility will be certified for 20 stations and will have sufficient capacity to serve the patients who chose to dialyze at this facility, thus this application to relocate stations to develop FKC Garner Dialysis will not adversely affect the patients remaining at the FMC White Oak facility.”

In Section Q, Form D, page 87, the applicant provides projected utilization for FMC White Oak, as illustrated in the following table.

FMC White Oak, Historical and Projected Utilization						
	Last Full FY CY2024	Interim Full FY CY 2025	Interim Full FY CY 2026	Interim Full FY CY 2027	1st Full FY CY 2028	2nd Full FY CY2029
# of Patients at the Beginning of the Year	73	72	74	77	58	61
# of Patients at the End of the Year	72	74	77	58	61	63
Average # of Patients during the Year	73	73	75	68	60	62

In Section D, pages 36-39, and Section Q, pages 88-89, the applicant provides the assumptions and methodology used to project utilization for FMC White Oak, which is summarized below.

- The applicant begins projections using the facility census as of December 31, 2024.
- The applicant project growth of the Wake County patient population using a 4.0% growth rate.
- The facility currently served a total of three Johnston County in-center patients. The applicant does not project any growth for the Johnston County patient population but adds those patients to the projections where appropriate.
- The facility serves one out of state in-center patient. The applicant states that this patient was a transient patient and the patient will not be added into any future patient population projections.
- The applicant will subtract the 19 Wake County patients and two Johnston County patients who have expressed their interest in transferring to FKC Garner Dialysis facility upon project completion.

	In-Center Patients
Begin with the Wake County patient population as of December 31, 2024.	68.0
Project the Wake County patient population forward one year to December 31, 2025.	$68.0 \times 1.040 = 70.7$
Add the 3 in-center patients from other counties. This is the projected ending census for Interim Year 1.	$70.7 + 3.0 = 73.7$
Project the Wake County patient population forward one year to December 31, 2026.	$70.7 \times 1.040 = 73.5$
Add the 3 in-center patients from other counties. This is the projected ending census for Interim Year 2.	$73.5 + 3.0 = 76.5$
Project the Wake County patient population forward one year to December 31, 2027.	$73.5 \times 1.040 = 76.5$
Subtract the 19 Wake County in-center patients projected to transfer to FKC Garner Dialysis upon certification.	$76.5 - 19.0 = 57.5$
Subtract the 2 Johnston County in-center patients projected to transfer to FKC Garner Dialysis upon certification.	$3.0 - 2.0 = 1.0$
Add the 1 in-center patient from other counties. This is the projected ending census for Interim Year 2.	$57.5 + 1.0 = 58.5$

The applicant projects to serve 58.5 patients on 13 stations, which is 4.50 patients per station per week ($58.5 \text{ patients} / 13 \text{ stations} = 4.50$), or 112.48% utilization as of December 31, 2027. This is assuming the facility would only have 13 stations. Table 9D: Dialysis Station Need Determination by Facility, page 138, of the 2025 SMFP indicates that FMC White Oak is eligible to apply for seven additional dialysis stations. The applicant states that it intends to apply for seven additional stations in November 2025 to backfill the stations proposed to be relocated to the new FKC Garner Dialysis facility. Therefore, the facility is expected to have sufficient capacity to serve its projected number of patients upon completion of this project.

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

- The applicant uses a growth rate of 4.0% which is higher than the growth rate for Wake County published in the 2025 SMFP, but less than the 4-Year Compound Annual Growth Rate (CAGR) of 9.67% for Wake County in-center patients at FMC White Oak.
- The applicant projects growth only in the Wake County patient population and adds patients from Johnston County after calculating the growth of Wake County patients.
- The applicant intends to backfill its dialysis stations to be relocated, thus ensuring adequate capacity to meet expected demand.

SW Wake County Dialysis

On page 41, the applicant states:

“Table 9D: Dialysis Station Need Determination by Facility in Chapter 9 of the 2025 SMFP does indicate that SW Wake Dialysis is eligible to apply for nine additional dialysis stations. The applicant intends to apply for nine additional stations in November 2025 to backfill the stations proposed to be relocated to the new FKC Garner Dialysis facility.

Upon completion of the proposed project and the application to backfill stations at SW Wake Dialysis, the facility will be certified for 30 stations and will have sufficient capacity to serve the patients who chose to dialyze at this facility, thus this application to relocate stations to develop FKC Garner Dialysis will not adversely affect the patients remaining at the SW Wake Dialysis facility.”

In Section Q, Form D, page 91, the applicant provides projected utilization for SW Wake County Dialysis, as illustrated in the following table.

SW Wake County Dialysis, Historical and Projected Utilization						
	Last Full FY CY2024	Interim Full FY CY 2025	Interim Full FY CY 2026	Interim Full FY CY 2027	1st Full FY CY 2028	2nd Full FY CY2029
# of Patients at the Beginning of the Year	114	105	106	107	95	96
# of Patients at the End of the Year	105	106	107	95	96	96
Average # of Patients during the Year	110	105	106	101	95	96

In Section D, pages 39-41, and Section Q, pages 92-93, the applicant provides the assumptions and methodology used to project utilization for SW Wake County Dialysis, which is summarized below.

- The applicant begins projections using the facility census as of December 31, 2024.
- The applicant project growth of the Wake County patient population using the Wake County 5-Year AACR of 0.9% as published in the 2025 SMFP.
- The facility currently served a total of two Johnston County in-center patients. The applicant does not project any growth for the Johnston County patient population but adds those patients to the projections where appropriate.
- The applicant will subtract the 13 Wake County patients who have expressed their interest in transferring to FKC Garner Dialysis facility upon project completion.

In Section D, page 40, the applicant provides projected utilization for SW Wake County Dialysis, as illustrated in the following table.

Begin with the Wake County patient population as of December 31, 2024.	103.0
Project the Wake County patient population forward one year to December 31, 2025.	$103.0 \times 1.040 = 103.9$
Add the 2 in-center patients from other counties. This is the projected ending census for Interim Year 1.	$103.9 + 2.0 = 105.9$
Project the Wake County patient population forward one year to December 31, 2026.	$103.9 \times 1.040 = 104.9$
Add the 2 in-center patients from other counties. This is the projected ending census for Interim Year 2.	$104.9 + 2.0 = 106.9$
Project the Wake County patient population forward one year to December 31, 2027.	$104.9 \times 1.040 = 105.8$
Subtract the 13 Wake County in-center patients projected to transfer to FKC Garner Dialysis upon certification.	$105.8 - 13.0 = 92.8$
Add the 2 in-center patients from other counties. This is the projected ending census for Interim Year 2.	$92.8 + 2.0 = 94.8$

The applicant projects to serve 94.8 patients on 21 stations, which is 4.51 patients per station per week ($94.8 \text{ patients} / 21 \text{ stations} = 4.51$), as of December 31, 2027. This is assuming the facility would only have 21 stations. Table 9D: Dialysis Station Need Determination by Facility, page 138, of the 2025 SMFP indicates that SW Wake County Dialysis is eligible to apply for nine additional dialysis stations. The applicant states that it intends to apply for nine additional stations in November 2025 to backfill the stations proposed to be relocated to the new FKC Garner Dialysis facility.

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

- The applicant uses a growth rate of 0.9% which is in line with the Wake County 5-Year AACR as published in the 2025 SMFP.
- The applicant projects growth only in the Wake County patient population and adds patients from Johnston County after calculating the growth of Wake County patients.
- The applicant intends to backfill its dialysis station to be relocated, thus ensuring adequate capacity to meet expected demand.

Access to Medically Underserved Groups

In Section D, page 41, the applicant states:

“...the relocation of existing stations from FMC White Oak and SW Wake Dialysis to FKC Garner Dialysis will not have any effect on the ability of any members of the above identified groups to have convenient access to dialysis care. The applicant is proposing to relocate existing stations and services within the same county, and the needs of the population to remain at the facility will be adequately addressed...”

The applicant adequately demonstrates that the needs of medically underserved groups that will continue to use in-center dialysis services will be adequately met following completion of the project for the following reasons:

- The applicant provides a statement of its intent to continue serving medically underserved populations.
- The applicant provides a projected estimate of the percentage of patients in medically underserved groups it anticipates serving.

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 needs of the population currently using the services to be reduced, eliminated or relocated will be adequately met following project completion for all the reasons described above.
- The applicant adequately demonstrates that the project will not adversely impact the ability of underserved groups to access these services following project completion for all the reasons described above.

- (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 develop a new 16-station dialysis facility, FKC Garner Dialysis, by relocating no more than nine dialysis stations from FMC White Oak and no more than seven dialysis stations from SW Wake Dialysis.

In Section E, page 43, 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 it could have chosen not to develop FKC Garner Dialysis. The applicant states that it chose to develop FKC Garner Dialysis as an effort to bring dialysis care and treatment closer to the patient's residence and shorten the patient commute to and from dialysis which enhances the patient's quality of life. Therefore, this is a less effective alternative.

- **Develop Fewer than 16 In-Center Dialysis Stations.** The applicant states that it did not choose to develop fewer than 16 in-center dialysis stations primarily because of the number of patients living in this area of Wake County and fewer than 16 stations would not meet the needs of those patients. Therefore, this is a less effective alternative.

On page 43, the applicant states that its proposal is the most effective alternative for the following reasons:

- The development of FKC Garner Dialysis will bring in-center dialysis closer to the patient's residence and shorten the patient commute
- The 48 patient letters of support for the project indicate that there are 48 patients who believe that the proposed facility would be more convenient for their dialysis care and treatment than the current dialysis facility.

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 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. The certificate holder shall develop a new 16-station dialysis facility, Fresenius Kidney Care Garner Dialysis, by relocating no more than seven in-center dialysis stations from Fresenius Kidney Care White Oak and no more than nine in-center dialysis stations from Southwest Wake County Dialysis.**
- 3. Upon completion of the proposed project, the certificate holder shall take the necessary steps to decertify seven in-center dialysis stations at Fresenius Kidney Care White Oak for a total of no more than 13 in-center stations at Fresenius Kidney Care White Oak upon project completion.**

4. Upon completion of the proposed project, the certificate holder shall take the necessary steps to decertify nine in-center dialysis stations at Southwest Wake County Dialysis for a total of no more than 21 in-center stations upon project completion.
 5. **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 June 1, 2026.
 6. 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 develop a new 16-station dialysis facility, FKC Garner Dialysis, by relocating no more than seven dialysis stations from FMC White Oak and no more than nine dialysis stations from SW Wake Dialysis.

Capital and Working Capital Costs

On Form F.1a in Section Q, page 94, the applicant projects the total capital cost of the project, as shown in the table below.

Construction/Renovation Contracts	\$2,595,450
Architect / Engineering Fees	\$232,544
Non-Medical Equipment	\$415,350
Furniture	\$166,250
Generator	\$107,316
Contingency	\$140,818
Total	\$3,657,728

In Section Q, page 95, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant states that the capital costs for this project were developed by the Fresenius Real Estate and Construction Services (RECS) team. Construction estimates are based upon a national database used by the RECS team.
- The applicant states that Architect and Engineering Fees are estimated at 11% of the proposed construction cost.
- The applicant states that the contingency amount is calculated at 5% of the sum of Construction and Architect / Engineering Fees.
- The applicant identifies the items that are included in each category.

In Section F, page 46, the applicant projects that start-up costs will be \$211,532 and initial operating expenses will be \$1,246,084 for a total working capital of \$1,457,617. On pages 46-47, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the following:

- The applicant states that start up costs are comprised of a four week supply of clinical supply/medications and staff salaries.
- The initial operating expenses are calculated as six months of the first-year expenses.

Availability of Funds

In Section F, page 44, the applicant states that the capital cost will be funded by accumulated reserves. Exhibit F-2 contains a letter dated September 15, 2025, from the Vice President of Corporate Tax - North America for Fresenius Medical Care Holdings, Inc. committing \$3,657,728 for the capital cost and any additional working capital necessary for the proposed project. Fresenius Medical Care Holdings, Inc., is the parent company of National Medical Care, Inc., Bio-Medical Applications of North Carolina, Inc. In Exhibit F.2, the Vice President of Corporate Tax - North America of Fresenius Medical Care Holdings, Inc states that their Q1 2025 Consolidated Balance Sheet reflects more than \$231 million in cash and total assets exceeding \$24 billion.

The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project based on the documentation in Exhibit F.2.

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, page 97, the applicant projects that revenues will exceed operating expenses in the first two full fiscal years following completion of the project, as shown in the table below.

FKC Garner Dialysis	1st Full FY	2nd Full FY
	CY2028	CY2029
Total # of Treatments	7,133	7,192
Total Gross Revenue	\$44,875,615	\$45,245,978
Total Net Revenue	\$2,538,681	\$2,559,633
Average Net Revenue per Treatment	\$356	\$356
Total Operating Costs	\$2,463,776	\$2,491,956
Average Operating Expense per Treatment	\$345	\$346
Net Income	\$74,905	\$67,677

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

The applicant proposes to develop a new 16-station dialysis facility, FKC Garner Dialysis, by relocating no more than seven dialysis stations from FMC White Oak and no more than nine dialysis stations from SW Wake Dialysis.

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

According to Table 9A on pages 119-120 of the Proposed 2026 SMFP, there are 21 existing or approved dialysis facilities in Wake County as shown in the following table:

Wake County			
Facility	Certified Stations 12/31/2024	# of In-Center Patients 12/31/2024	Utilization Rate 12/31/2024
BMA of Fuquay Varina Kidney Center	29	93	80.17%
BMA of Raleigh Dialysis	50	120	60.00%
Cary Kidney Center	29	84	72.41%
Downtown Raleigh Dialysis	0	18	0.00%
FMC Eastern Wake	15	60	100.00%
FMC Morrisville	13	45	86.54%
FMC New Hope Dialysis	36	116	80.56%
FMC Northern Wake	20	57	71.25%
FMC Wake Dialysis Clinic	50	150	75.00%
Fresenius Kidney Care Holly Springs	10	36	90.00%
Fresenius Kidney Care Knightdale	0	0	0.00%
Fresenius Medical Care Apex	20	66	82.50%
Fresenius Medical Care Central Raleigh	19	50	65.79%
Fresenius Medical Care Millbrook	17	63	92.65%
Fresenius Medical Care Rock Quarry	0	0	0.00%
Fresenius Medical Care White Oak	20	72	90.00%
Oak City Dialysis	32	78	60.94%
Southwest Wake County Dialysis	30	105	87.50%
Tarheel Place Dialysis	0	0	0.00%
Wake Forest Dialysis Center	21	81	96.43%
Zebulon Kidney Center	30	79	65.83%

Source: Table 9A of the Proposed 2026 SMFP, pages 119-120.

In Section G, page 52, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved services in Wake County. The applicant states:

“The applicant is not proposing to develop new dialysis stations by this proposal. The applicant is instead proposing to relocate existing certified dialysis stations within Wake County. These stations have been previously approved and do not duplicate services.”

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 proposal would not result in an increase in the number of certified dialysis stations in Wake County.
- The applicant adequately demonstrates that the proposed relocation of existing certified dialysis stations is needed 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.

C

The applicant proposes to develop a new 16-station dialysis facility, FKC Garner Dialysis, by relocating no more than seven dialysis stations from FMC White Oak and no more than nine dialysis stations from SW Wake Dialysis.

In Section Q, on Form H, page 104, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	1st Full FY	2nd Full FY
	CY2028	CY2029
Administrator (FMC Clinic Manager)	1.00	1.00
Registered Nurses (RNs)	2.00	2.00
Technicians (PCT)	4.00	4.00
Dietician	0.50	0.50
Social Worker	0.50	0.50
Maintenance	0.50	0.50
Administration/Business Office	0.50	0.50
FMC Director of Operations	0.15	0.15
FMC Chief Technician	0.15	0.15
FMC In-Service	0.15	0.15
Total	9.45	9.45

The assumptions and methodology used to project staffing are provided in Section Q, page 105. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.4 in Section Q. In Section H, pages 53-54,

the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

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

- The applicant projects sufficient operating expenses for the staff proposed by the applicant.
- The applicant describes the methods it uses to attract qualified staff which will enable the facility to maintain staffing levels.
- The applicant describes the required qualifications for staff, continuing education, and other training programs.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to develop a new 16-station dialysis facility, FKC Garner Dialysis, by relocating no more than seven dialysis stations from FMC White Oak and no more than nine dialysis stations from SW Wake Dialysis.

Ancillary and Support Services

In Section I, page 55, the applicant identifies the necessary ancillary and support services for the proposed services. In Section I, pages 55-56, 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 states that ancillary and support services will be provided by local facility staff or the corporate structure of Fresenius Medical Care.
- The applicant states that other ancillary and support services will be contracted such as housekeeping/linen and building maintenance/groundskeeping.

Coordination

In Section I, page 60, 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 because the applicant has existing relationships with local health care and social service providers in the service area.

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.

C

The applicant proposes to develop a new 16-station dialysis facility, FKC Garner Dialysis, by relocating no more than seven dialysis stations from FMC White Oak and no more than nine dialysis stations from SW Wake Dialysis.

In Section K, page 63, the applicant states that the project involves renovating approximately 9,669 square feet of existing space. Line drawings are provided in Exhibit K-2.

On pages 65-66, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site. Supporting documentation is provided in Exhibit K-4. The site appears to be suitable for the proposed dialysis facility based on the applicant's representations and supporting documentation.

In Section K, pages 63-64, 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 finding an existing space which is suitable for renovation and use for a dialysis facility eliminates the cost of building a new space and renovations can be accomplished more cost effectively than building a new structure.
- The applicant states that it will rely upon the extensive experience of Fresenius Medical Care RECS team to ensure project costs are reasonable and accurate.
- The applicant states that the Fresenius RECS team designs facilities with energy efficiency and cost savings in mind.

In Section K, page 64, 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 because the applicant states that the cost of development of the dialysis facility will be the responsibility of the applicant and not passed on to the

patient. The applicant states this project will not increase costs or charges to the public for the proposed services.

In Section K, pages 64-65, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

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 68, the applicant provides the historical payor mix during CY2024 for FMC White Oak, the facility from which the existing dialysis stations will be relocated, as shown in the table below.

Payor Source	FMC White Oak, CY2024	
	In-Center Dialysis	
	# of Patients	% of Total
Self -Pay	1.5	2.10%
Insurance	8.4	11.65%
Medicare	55.7	77.30%
Medicaid	3.1	4.32%
Other	3.3	4.63%
Total	72.0	100.00%

In Section L, page 68, the applicant provides the historical payor mix during CY2024 for SW Wake Dialysis, the facility from which the existing dialysis stations will be relocated, as shown in the table below.

Payor Source	SW Wake Dialysis, CY2024	
	In-Center Dialysis	
	# of Patients	% of Total
Self -Pay	6.4	6.07%
Insurance	4.7	4.46%
Medicare	77.9	74.18%
Medicaid	11.2	10.67%
Other	4.8	4.61%
Total	105.0	100.00%

In Section L, page 69, the applicant provides the following comparison for FMC White Oak.

FMC White Oak	Last Full FY before Submission of the Application	
	Percentage of Total Patients Served	Percentage of the Population of the Service Area
Female	50.7%	51.0%
Male	49.3%	49.0%
Unknown	-	-
64 and Younger	43.5%	86.6%
65 and Older	56.5%	13.4%
American Indian	-	0.8%
Asian	2.9%	9.4%
Black or African American	55.1%	20.6%
Native Hawaiian or Pacific Islander	-	0.1%
White or Caucasian	42.0%	66.3%
Other Race	-	14.4%

In Section L, page 70, the applicant provides the following comparison for SW Wake Dialysis.

SW Wake Dialysis	Last Full FY before Submission of the Application	
	Percentage of Total Patients Served	Percentage of the Population of the Service Area
Female	38.7%	51.0%
Male	61.3%	49.0%
Unknown	-	-
64 and Younger	77.4%	86.6%
65 and Older	22.6%	13.4%
American Indian	0.9%	0.8%
Asian	2.8%	9.4%
Black or African American	78.3%	20.6%
Native Hawaiian or Pacific Islander	0.9%	0.1%
White or Caucasian	17.0%	66.3%
Other Race	-	14.4%

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 70, the applicant states it has no such obligation.

In Section L, page 70, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 71, 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.

Primary Payor Source at Admission	FKC Garner Dialysis, CY2029	
	In-center Dialysis	
	# of Patients	% of Total
Self-Pay	2.0	4.09%
Insurance	3.9	8.05%
Medicare	37.0	75.74%
Medicaid	3.7	7.50%
Other*	2.3	4.62%
Total	48.8	100.00%

Source: Section L, page 71.

*Other includes all other reimbursement sources, including VA.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 4.09% of services will be provided to self-pay patients, 75.74% to Medicare patients and 7.50% to Medicaid patients.

On page 71, 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:

- The applicant states that it relied on an average of the recent performance of FMC White Oak and SW Wake Dialysis to determine the payor mix for FKC Garner Dialysis.
- The applicant states that it calculates payor mix based upon treatment volumes.
- The applicant states that the payor source is determined based upon treatment reimbursement.

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 73, 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 develop a new 16-station dialysis facility, FKC Garner Dialysis, by relocating no more than seven dialysis stations from FMC White Oak and no more than nine dialysis stations from SW Wake Dialysis.

In Section M, page 74, 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 applicant's statement and the inclusion of a copy of a letter sent to Wake Technical Community College offering the facility as a training site for nursing students.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to develop a new 16-station dialysis facility, FKC Garner Dialysis, by relocating no more than seven dialysis stations from FMC White Oak and no more than nine dialysis stations from SW Wake Dialysis.

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

According to Table 9A on pages 119-120 of the Proposed 2026 SMFP, there are 21 existing or approved dialysis facilities in Wake County as shown in the following table:

Wake County			
Facility	Certified Stations 12/31/2024	# of In-Center Patients 12/31/2024	Utilization Rate 12/31/2024
BMA of Fuquay Varina Kidney Center	29	93	80.17%
BMA of Raleigh Dialysis	50	120	60.00%
Cary Kidney Center	29	84	72.41%
Downtown Raleigh Dialysis	0	18	0.00%
FMC Eastern Wake	15	60	100.00%
FMC Morrisville	13	45	86.54%
FMC New Hope Dialysis	36	116	80.56%
FMC Northern Wake	20	57	71.25%
FMC Wake Dialysis Clinic	50	150	75.00%
Fresenius Kidney Care Holly Springs	10	36	90.00%
Fresenius Kidney Care Knightdale	0	0	0.00%
Fresenius Medical Care Apex	20	66	82.50%
Fresenius Medical Care Central Raleigh	19	50	65.79%
Fresenius Medical Care Millbrook	17	63	92.65%
Fresenius Medical Care Rock Quarry	0	0	0.00%
Fresenius Medical Care White Oak	20	72	90.00%
Oak City Dialysis	32	78	60.94%
Southwest Wake County Dialysis	30	105	87.50%
Tarheel Place Dialysis	0	0	0.00%
Wake Forest Dialysis Center	21	81	96.43%
Zebulon Kidney Center	30	79	65.83%

Source: Table 9A of the Proposed 2026 SMFP, pages 119-120.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 75, the applicant states:

“The applicant does not expect this proposal to have any effect on the competitive climate in Wake County. The applicant does not project to serve dialysis patients currently being served by another provider. The projected patient population for the facility begins with the current patient population, projected patient transfers, and growth of that population

consistent with the Wake County Five Year Average Annual Change Rate published in the 2025 SMFP. This application addresses the needs of an existing patient population, and the proposed project will help to ensure that patients choosing to receive their treatment at BMA facilities in Wake County will continue to have access to high quality dialysis care in a location that is accessible to them.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 76, the applicant states:

“This is a proposal to relocate 16 existing in-center dialysis stations to develop a new facility in Garner in Wake County. 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 of the area in a convenient setting. As a result, these patients will have a shorter commute to and from dialysis treatment. This is an immediate and significantly positive impact to the patients of the area.”

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

Regarding the impact of the proposal on quality, in Section N, page 76, the applicant states:

“Quality of care is always in the forefront at Fresenius Medical Care-related facilities. Quality care is not negotiable. Fresenius Medical Care, parent organization for this facility, expects every facility to provide high quality care to every patient at every treatment. Our organizational mission statement captures this sentiment very well:

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

See also Section O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 76, the applicant states:

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

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

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

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

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

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, pages 106-109, 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 133 of this type of facility located in North Carolina.

In Section O, page 81, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents related to quality of care in any of these facilities. After reviewing and considering information provided by the applicant and considering the quality of care provided at all 133 facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

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

C

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

10A NCAC 14C .2203 PERFORMANCE STANDARDS

(a) An applicant proposing to establish a new dialysis facility for in-center hemodialysis services shall document the need for at least 10 dialysis stations based on utilization of 2.8 in-center patients per station per week as of the end of the first full fiscal year of operation following certification of the facility. An applicant may document the need for fewer than 10 stations if the application is submitted in response to an adjusted need determination in the State Medical Facilities Plan for fewer than 10 stations.

-C- In Section C, page 32, the applicant projects 48.4 in-center patients will be served by the proposed facility by the end of the first full fiscal year, FY2028, for utilization rate of 3.03 in-center patients per station per week or 75.62% ($48.4 \text{ patients} / 16 \text{ stations} = 3.025 \text{ patients per station} / 4 = 0.7562$) The projected utilization of 3.03 patients per station per week exceeds the 2.8 in-center patients per station threshold required by this rule.

(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.

-NA- The applicant is proposing to establish a new ESRD facility.

(c) An applicant shall provide all assumptions; including the methodology by which patient utilization is projected. 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.

(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 is not proposing to increase the number of home hemodialysis stations in a dialysis facility dedicated to home hemodialysis or peritoneal dialysis training.

(e) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.

-C- In Section Q, pages 85-86, 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.