

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: March 7, 2025

Findings Date: March 7, 2025

Project Analyst: Tanya M. Saporito

Co-Signer: Michael J. McKillip

Project ID #: M-12586-25

Facility: Fresenius Kidney Care Spring Lake Dialysis

FID #: 250045

County: Cumberland

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

Project: Develop a new dialysis facility by relocating no more than 6 dialysis stations from FMC Services of West Fayetteville and no more than 9 dialysis stations from FKC Rockfish for a total of no more than 15 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 “the applicant” or BMA) proposes to develop a new 15-station dialysis facility, Fresenius Kidney Care Spring Lake Dialysis (FKC Spring Lake), by relocating six dialysis stations from FMC Dialysis Services of West Fayetteville (FMC West Fayetteville) and nine dialysis stations from Fresenius Kidney Care Rockfish (FKC Rockfish). The proposed facility will offer only in-center hemodialysis (ICHHD) upon project completion.

The applicant does not propose to develop any beds or services or acquire any medical equipment for which there is a need determination in the 2025 SMFP. There is one policy applicable to this review: *Policy GEN-4*, on page 30 of the 2025 SMFP states:

“Any person proposing a capital expenditure greater than \$4 million to develop, replace, renovate or add to a health service facility pursuant to G.S. § 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. § 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. § 131E-184 is required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control.”

The proposed capital expenditure for this project is greater than \$4 million. In Section B, pages 19-21, the applicant describes the methods by which BMA will maintain efficient energy operations and therefore contain costs.

The applicant adequately demonstrates that the application includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation. The application is consistent with Policy GEN-4.

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.

- (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 15-station dialysis facility by relocating no more than six dialysis stations from FMC West Fayetteville and no more than nine dialysis stations from FKC Rockfish.

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 Cumberland County. Thus, the service area for this facility consists of Cumberland 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 table, 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 West Fayetteville and FKC Rockfish as part of this proposal:

**FMC West Fayetteville, Historical Patient Origin
CY 2024**

COUNTY	# IN-CTR. PATIENTS	% OF TOTAL
Cumberland	152.0	100.0%
Total	152.0	100.0%

FKC Rockfish Historical Patient Origin, CY 2024

COUNTY	# IN-CTR. PATIENTS	% OF TOTAL
Cumberland	81.0	85.3%
Hoke	12.0	12.6%
Lincoln	1.0	1.1%
Robeson	1.0	1.1%
Total	95.0	100.0%

The following table, from Section C page 25, illustrates projected patient origin for the proposed FKC Spring Lake facility for the second full fiscal year (FY) of operation, CY 2029:

FKC Spring Lake Projected Patient Origin, CY 2029

COUNTY	# IN-CTR. PATIENTS	% OF TOTAL
Cumberland	33.0	76.7%
Harnett	9.0	21.0%
Hoke	1.0	2.3%
Total	43.0	100.0%

In Section C, pages 25-26 the applicant provides the assumptions and methodology used to project patient origin, summarized as follows:

- In Exhibit C-3 the applicant provides 42 letters of support signed by 32 in-center patients residing in Cumberland County, nine patients residing in Harnett County and one in-center patient residing in Hoke 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 residence ZIP codes of those patients who signed letters of support. The applicant states each of those residence ZIP codes are close to the proposed location of the proposed facility, in the northern part of Cumberland County which borders both Harnett and Hoke Counties. See the table on page 25 that illustrates these patient residence ZIP codes.

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 Cumberland, Harnett and Hoke 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 closer to the proposed facility that will be located in northern Cumberland County.
- The existing BMA facilities in Cumberland County are closer to the center of Fayetteville and to the west and south of the center of Fayetteville.

Analysis of Need

In Section C, pages 27-29 the applicant explains why it believes the population projected to utilize the proposed in-center dialysis services needs those services, summarized as follows:

- The applicant examined ESRD patient data from the 2025 SMFP that shows the total ESRD patient population increased by 8.83% between December 31, 2022 and December 31, 2023, which is 68 ESRD patients.

- The applicant states the total number of ESRD patients in Cumberland County is projected to increase by 12 patients in 2024, which shows the ESRD patient population in Cumberland County is increasing.
- The applicant examined U.S. Census data which shows the over 65 population in Cumberland County, the population most likely to need dialysis services, is 13.3% of the total population in the county.
- The applicant states patients with end stage renal disease or chronic kidney disease (CKD) require dialysis treatments on a regular basis, typically three times per week to maintain life. Given the necessity of regular treatment, the distance a patient and family members must travel impacts their quality of life and the care they receive. Developing an in-center dialysis facility in a location in Cumberland County that is closer to patients residing in the northern part of the county or in contiguous Harnett and Hoke counties will allow the applicant to provide necessary dialysis services to those patients who need those services.

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

Projected Utilization

In Section Q, Form C, page 85 the applicant provides projected utilization of FKC Spring Lake for the first two OYs, CYs 2028-2029, as illustrated in the following table:

	1 ST FULL OY CY 2028	2 ND FULL OY CY 2029
# Pts. at Beginning of Year	42	42
# Pts. at End of Year	42	43
Avg. # Pts. During the Year	42	43
# Treatments/Pt./Year	148	148
Total # Treatments	6,252	6,323

In Section Q, following Form C, the applicant provides the assumptions and methodology used to project utilization, summarized as follows:

- The applicant provides the following table from application page 86 that illustrates ZIP code residence of those patients who signed letters of support to transfer their care to the proposed facility:

FACILITY	PATIENT RESIDENCE ZIP CODES						TOTALS
	28302	28303	28305	28311	27376	28390	
FKC West Fayetteville	3	12		3			18
FKC Rockfish		8	1	1	1		11
FMC Anderson Creek		2		2		6	10
FMC North Ramsey						3	3
Total	3	22	1	6	1	9	42

- The applicant projects growth in the Cumberland County patient population by applying the 1.5% Cumberland County Average Annual Change Rate (AACR) as published in the 2025 SMFP.
- The applicant does not project growth in the Harnett and Hoke County patient populations but adds these patients to projected utilization at specific points in time.
- The applicant projects the facility will be certified as of December 31, 2027; therefore, the first full operating year (OY) is CY 2028, and the second full OY is CY 2029. See the table that illustrates the in-center methodology on page 26 of the application. By the end of the first OY, the applicant projects to serve 42.5 in-center patients. By the end of the second OY the applicant projects to served 43.0 in-center patients. The applicant states it will not serve home hemodialysis (HHD) patients at the proposed facility. Any patients who need HHD services will be referred to Fayetteville Kidney Center.

The following table from page 87 of the application illustrates projected utilization:

Begin with Cumberland County patient population who have signed letters of support to transfer their care to the proposed facility upon project completion, 12/31/27.	32.0
Project Cumberland County patient population forward one year to December 31, 2028.	$32.0 \times 1.015 = 32.5$
Add patients from Harnett and Hoke Counties. This is the end of Operating Year one.	$32.5 + 10 = 42.5$
Project Cumberland County patient population forward one year to December 31, 2029.	$32.5 \times 1.015 = 33.0$
Add patients from Harnett and Hoke Counties. This is the end of Operating Year two.	$33.0 + 10 = 43.0$

Based on the calculations above, by the end of OY 1, FKC Spring Lake is projected to dialyze 42.5 patients on 15 in-center stations, or a utilization rate of 71% [$42.5 / 15 = 2.833$. $2.833 / 4 = 0.708$]. By the end of OY 2 FKC Spring Lake is projected to dialyze 43.0 patients on 15 in-center stations, or a utilization rate of 72% [$43 / 15 = 2.867$. $2.867 / 4 = 0.717$].

The projected utilization of 2.83 patients per station per week at the end of OY 1 meets the minimum standard of 2.8 in-center patients per station per week 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 Spring Lake facility.

- The applicant's projected utilization in the first two years of operation is based on and supported by the 5-Year AACR for Cumberland County.
- The applicant projects growth only in the Cumberland County patient population and adds patients from Harnett and Hoke counties after calculating growth of Cumberland County patients.

Access to Medically Underserved Groups

In Section C, pages 31-32, the applicant states,

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

The applicant states the proposed services will be made available to all residents in the service area without qualifications. The facility will serve patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability and socioeconomic groups of patients in need of dialysis. In Section C, page 32 the applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

MEDICALLY UNDERSERVED GROUPS	PERCENTAGE OF TOTAL PATIENTS
Low income persons	38.4%
Racial and ethnic minorities	80.4%
Women	48.2%
Persons with disabilities	9.4%
Persons 65 and older	48.2%
Medicare beneficiaries	32.1%
Medicaid recipients	37.5%

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 15-station dialysis facility by relocating no more than six dialysis stations from FMC West Fayetteville and no more than nine dialysis stations from FKC Rockfish.

In Section D, pages 37-40, the applicant explains why it believes the needs of the population presently utilizing the services to be relocated will be met following project completion, summarized as follows:

FKC West Fayetteville

In Section D, page 35, the applicant states FKC West Fayetteville will relocate six in-center dialysis stations to the proposed FKC Spring Lake, and provides the following projected utilization for FKC West Fayetteville following the station relocation:

In Section D, page 38, the applicant provides a table showing the projected utilization for FKC West Fayetteville through the first two project years, as summarized below:

Begin with the Cumberland County patient population as of December 31, 2024.	152.0
Project the Cumberland County patient population forward one year to December 31, 2025.	$152.0 \times 1.015 = 154.3$
Project the Cumberland County patient population forward one year to December 31, 2026.	$154.3 \times 1.015 = 156.6$
Project the Cumberland County patient population forward one year to December 31, 2027.	$156.6 \times 1.015 = 158.9$
Subtract the 18 in-center patients projected to transfer to FKC Spring Lake.	$158.9 - 18.0 = 140.9$
Project Cumberland County patient population forward one year to December 31, 2028. This is the end of OY one.	$140.9 \times 1.015 = 143.1$
Project Cumberland County patient population forward one year to December 31, 2028. This is the end of OY two.	$143.1 \times 1.015 = 145.2$

The assumptions and methodology for projected utilization at FKC West Fayetteville are provided in Section D, pages 37 -38, summarized as follows:

- Projections for patient utilization begin with the patient population at FKC West Fayetteville as of December 31, 2024.
- The applicant applies the Cumberland County Five Year AACR of 1.5% as published in the 2025 SMFP to project growth in the patient population.
- The applicant subtracts from the patient census the number of patients who indicated an intent to transfer their care to the proposed FKC Spring Lake facility.

Based on the information above, by the end of OY 1 FKC West Fayetteville is projected to dialyze 143 in-center patients (rounded) on 34 in-center stations, which is 105% utilization [$143 / 34 = 4.21$. $4.21 / 4 = 1.05$].

On page 39, the applicant states it will apply for six additional stations at FKC West Fayetteville pursuant to the Facility Need Determination in the 2025 SMFP.

FKC Rockfish

In Section D, page 40, the applicant provides a table showing the projected utilization for FKC Rockfish through the first two project years, as summarized below:

Begin with the Cumberland County patient population as of December 31, 2024.	81.0
Project the Cumberland County patient population forward one year to December 31, 2025.	$81.0 \times 1.015 = 82.2$
Add the 13 in-center patients from other counties. This is the projected census for interim year one.	$82.2 + 13.0 = 95.2$
Project the Cumberland County patient population forward one year to December 31, 2026.	$82.2 \times 1.015 = 83.4$
Add the 13 in-center patients from other counties. This is the projected census for interim year two.	$83.4 + 13.0 = 96.4$
Project the Cumberland County patient population forward one year to December 31, 2027.	$83.4 \times 1.015 = 84.7$
Subtract the 10 Cumberland County in-center patients projected to transfer to FKC Spring Lake.	$84.7 - 10.0 = 74.7$
Subtract the one Hoke County in-center patient projected to transfer to FKC Spring Lake.	$12.0 - 1 = 11.0$
Add 12 in-center patients from other counties. This is the projected ending census for interim year three.	$74.7 + 12 = 86.7$
Project Cumberland County patient population forward one year to December 31, 2028.	$74.7 \times 1.015 = 75.8$
Add 12 in-center patients from other counties. This is the projected ending census for OY one.	$75.8 + 12 = 87.8$
Project Cumberland County patient population forward one year to December 31, 2029.	$75.8 \times 1.015 = 77.0$
Add 12 in-center patients from other counties. This is the projected ending census for OY two.	$77.0 + 12 = 89.0$

The assumptions and methodology for projected utilization at FKC Rockfish are provided in Section D, page 39, summarized as follows:

- Projections for patient utilization begin with the patient population at FKC Rockfish as of December 31, 2024.
- The applicant applies the Cumberland County Five Year AACR of 1.5% as published in the 2025 SMFP to project growth in the patient population.
- The applicant states the facility served a total of 14 in-center patients residing in the following counties: Hoke (12), Lincon (1) and Robeson (1). The applicant states Hoke and Robeson counties are contiguous to Cumberland County and thus it is reasonable to conclude that those patients would continue dialyzing at FKC Rockfish as a function of patient choice. The applicant does not project growth in that patient population but adds them at appropriate points in time.
- The applicant assumes the one Lincoln County patient was a transient patient and thus does not account for this patient in its projections.
- The applicant subtracts from the patient census the number of patients who indicated an intent to transfer their care to the proposed FKC Spring Lake facility.

Based on the information above, by the end of OY 1 FKC Rockfish is projected to dialyze 86.7 in-center patients on 16 in-center stations, which is 135.5% utilization [$86.7 / 16 = 5.42$. $5.42 / 4 = 1.35$].

On page 41, the applicant states it will apply for nine additional stations at FKC Rockfish pursuant to the Facility Need Determination in the 2025 SMFP.

Access to Medically Underserved Groups

In Section D, page 41 the applicant adequately demonstrates that the needs of medically underserved groups that will continue to use dialysis services at FKC West Fayetteville and FKC Rockfish will continue to be adequately met following the relocation of stations as proposed in this application, summarized as follows:

- The applicant states that the relocation of stations from FKC West Fayetteville and FKC Rockfish will have no effect on the ability of low-income persons, racial and ethnic minorities, women, disabled persons, and other under-served groups and the elderly to obtain access to dialysis services.
- The applicant provides a table on page 41 to illustrate projected utilization of those groups at both FKC West Fayetteville and FKC Rockfish following the station relocation.

The applicant adequately demonstrates the needs of medically underserved groups will continue to be adequately met following project completion based on the applicant's history of providing dialysis care to these 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 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 15-station dialysis facility by relocating no more than six dialysis stations from FMC West Fayetteville and no more than nine dialysis stations from FKC Rockfish.

In Section E, page 44, 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 considered not developing FKC Spring Lake but determined it would not effectively serve those Cumberland County residents who reside in the northern part of the county, as well as those patients in contiguous Harnett and Hoke counties who would have a choice of a facility closer to their residence.
- Develop FKC Spring Lake with fewer than 15 stations: The applicant states it based the decision regarding the number of stations to develop at the proposed facility based on the needs of the patients in the service area.

- Develop FKC Spring Lake with more than 15 stations: The applicant states it based the decision regarding the number of stations to develop at the proposed facility based on the needs of the patients in the service area.
- Develop FKC Spring Lake with home hemodialysis training and support services – The applicant states a home therapy program would have added additional space and capital investment. The applicant currently provides home therapy services at its Fayetteville Kidney Center facility in Cumberland County to both home hemodialysis and home peritoneal dialysis patients. Therefore, including space for home therapy treatment at FCK Spring Lake would be more costly and less effective for both the applicant and its patients.

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

- The applicant states that its proposal is the most effective alternative because a facility located in another area of Cumberland County would not address the need of the patients it serves.
- 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 15-station dialysis facility, FKC Spring Lake, by relocating no more than six dialysis stations from FMC Services of West Fayetteville and no more than nine dialysis stations from FKC Rockfish.**
- 3. Upon completion of the proposed project, the certificate holder shall take the necessary steps to decertify six stations at FMC Services of West Fayetteville for a total of no more than 34 in-center stations at FMC West Fayetteville upon project completion.**

4. Upon completion of the proposed project, the certificate holder shall take the necessary steps to decertify nine stations at FKC Rockfish for a total of no more than 16 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 August 1, 2025.

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 15-station dialysis facility by relocating no more than six dialysis stations from FMC West Fayetteville and no more than nine dialysis stations from FKC Rockfish.

Capital and Working Capital Costs

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

FKC Spring Lake Proposed Capital Cost	
Construction Costs	\$3,008,294
Architect/Engineering Fees	\$270,747
Non-Medical Equipment	\$490,350
Furniture	\$174,525
Other (Generator)	\$26,339
Other (Contingency)	\$163,952
Total	\$4,134,207

In Section Q, page 96 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 the construction cost estimates were developed by the Fresenius Real Estate and Construction Services team, and figures are based on national database figures.
- The applicant states architect and engineering fees are estimated at 9% of the proposed construction cost.
- Non-medical equipment and other furniture costs include those items and systems necessary for dialysis operations.

In Section F, pages 47-49, the applicant projects that start-up costs will be \$177,861 and initial operating expenses will be \$1,083,261 for a total working capital of \$1,261,122. On pages 48-49 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 it may be six months before cash in-flow will exceed cash out-flow and has incorporated that into its initial operating expenses.
- The applicant states clinical staff for the proposed facility will transfer from nearby BMA facilities, resulting in minimal initial staffing expenses. However, the applicant projects start-up costs as if the clinical positions are new staff positions, resulting in a conservative estimate of anticipated costs.
- The applicant calculates initial operating expenses based on six months of first year expenses.

Availability of Funds

In Section F, page 47 the applicant states that the capital cost will be funded with the corporate accumulated reserves of Bio-Medical Applications of North Carolina, Inc. In Exhibit F-2 the applicant provides a January 15, 2025 letter from the VP Corporate Tax North America of Fresenius Medical Care Holdings, Inc., the ultimate parent company of BMA, confirming the availability of sufficient funds for the capital and working capital costs for the proposed project. That same letter commits the funds to the project development.

The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project based on the information provided in the application and the funding letter provided 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, the applicant projects that revenues will not exceed operating expenses in the first two full fiscal years (FY), calendar years (CY) 2028-2029 following project completion, as shown in the following table:

	1 ST OY CY 2028	2 ND OY CY 2029
Total # of Treatments	6,255	6,333
Gross Revenue	\$39,349,261	\$39,841,738
Net Revenue	\$1,980,007	\$2,002,676
Avg. Net Revenue/Treatment	\$317	\$316
Operating Costs	\$2,166,522	\$2,186,738
Avg. Operating Cost/Treatment	\$346	\$345
Net Income	(\$186,515)	(\$184,062)

Although the applicant's financial pro forma forms project a loss in the first two full fiscal years following project completion, the applicant states this is due to the cost of developing a new facility from the ground up. In Section Q, page 99 the applicant states:

"... in an effort to develop the new facility in the desired location, BMA elected to build new space for the proposed facility rather than renovating existing space.

As the opportunity presents itself, BMA will be adding capacity and increasing our patient census at the facility which will help in our efforts to return the facility to a profitable status. In the meantime, our parent company, Fresenius Medical Care Holdings, Inc. is prepared to absorb the financial losses of the FKC Spring Lake Dialysis."

In Exhibit F.3 the applicant provides the unaudited balance sheets for Fresenius Medical Care Holdings, Inc. and its Subsidiaries, which show sufficient assets to fund the proposed project.

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.

C

The applicant proposes to develop a new 15-station dialysis facility by relocating no more than six dialysis stations from FMC West Fayetteville and no more than nine dialysis stations from FKC Rockfish.

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

Table 9A on page 121 of the 2025 SMFP shows six existing or approved dialysis facilities in Cumberland County as shown in the following table:

FACILITY	# STATIONS	# PATIENTS	% UTILIZATION
Fayetteville Kidney Center	57	164	71.93%
FMC Dialysis Services North Ramsey	54	128	59.26%
FMC Dialysis Services South Ramsey	56	158	70.54%
FMC Services of West Fayetteville	40	137	85.63%
FKC Hope Mills*	0	0	0.00%
FKC Rockfish	25	88	88.00%

In Section G, pages 53-54, the applicant explains why it believes its proposal would not result in the necessary duplication of existing or approved dialysis services in Cumberland County. The applicant states:

“BMA is the only dialysis provider of in-center dialysis services in Cumberland County. 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 Cumberland 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 Cumberland County.
- The applicant adequately demonstrates that the proposed relocation of the existing certified dialysis stations is needed in Cumberland 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 15-station dialysis facility by relocating no more than six dialysis stations from FMC West Fayetteville and no more than nine dialysis stations from FKC Rockfish.

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

POSITION	1 ST OY CY 2028	2 ND OY CY 2029
Administrator	1.00	1.00
Registered Nurses (RNs)	2.00	2.00
Technicians	3.00	3.00
Dietician	0.80	0.80
Social Worker	0.80	0.80
Maintenance	0.60	0.60
Administration/Business Office	1.00	1.00
Other (FMC Dir. of Operations)	0.15	0.15
Other (FMC Chief Technician)	0.12	0.12
Other (FMC In-Service)	0.15	0.15
Total	9.62	9.62

Source: Section Q, Form H, page 106

The assumptions and methodology used to project staffing are provided following Form H in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.4 in Section Q. In Section H, pages 55-56 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 states projected staffing is based on what is necessary for dialysis facility operation.
- The applicant projects sufficient operating expenses for the staff proposed by the applicant.
- 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 15-station dialysis facility by relocating no more than nine dialysis stations from FMC West Fayetteville and no more than 9 dialysis stations from FKC Rockfish.

Ancillary and Support Services

In Section I, page 57, the applicant identifies the necessary ancillary and support services for the proposed services. In Section I, pages 57-62 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 following the development of the proposed facility.

Coordination

In Section I, page 62, 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 BMA currently operates five dialysis facilities in Cumberland County and has existing relationships with local health care and social service providers in place. Those same relationships will be extended to FKC Spring Lake.

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 develop a new 15-station dialysis facility by relocating no more than six dialysis stations from FMC West Fayetteville and no more than nine dialysis stations from FKC Rockfish.

In Section K, page 65 the applicant states that the project involves constructing 8,466 square feet of new space. Line drawings are provided in Exhibit K-2.

In Section K, pages 65-66 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 the Fresenius Real Estate and Construction Services team designs BMA facilities with energy efficiency and cost savings in mind.

- The applicant states it selected the site for the convenience of the patient population it proposes to serve, because the site is in close proximity to a “*significant number of patients*” who are projected to utilize the facility.

In Section K, page 66, 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 development of a new facility is a necessary part of doing business and the associated costs are not passed on to the patient.
- The applicant states the project will not increase costs or charges to the public for the proposed services.

In Section K, pages 66-67, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit K.4.

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 70, the applicant provides the historical payor mix during CY 2023 for its existing dialysis services at FMC West Fayetteville and FKC Rockfish, the two facilities from which stations are proposed to be relocated, as shown in the following tables:

FMC West Fayetteville Historical Payor Mix, CY 2023

PAYOR SOURCE	# OF PT.S	% OF TOTAL
Self-Pay	2.20	1.63%
Insurance*	7.40	5.40%
Medicare*	105.40	76.92%
Medicaid*	10.70	7.84%
Other^	11.20	8.21%
Total	137.00	100.00%

*Includes any managed care plans

^On page 70 the applicant states "other" includes all other reimbursement sources, including VA

FKC Rockfish Historical Payor Mix, CY 2023

PAYOR SOURCE	# OF PT.S	% OF TOTAL
Self-Pay	1.4	1.58%
Insurance*	5.2	5.91%
Medicare*	58.3	66.26%
Medicaid*	7.8	8.86%
Other^	15.3	17.39%
Total	88.0	100.00%

*Includes any managed care plans

^On page 70 the applicant states "other" includes all other reimbursement sources, including VA

In Section L, pages 70-71 the applicant provides the following comparison for both FMC West Fayetteville and FKC Rockfish:

In Section L, page 71, the applicant provides the following comparison.

FMC West Fayetteville

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	47.5%	50.5%
Male	52.5%	49.5
Unknown		
64 and Younger	48.2%	86.7%
65 and Older	51.8%	13.3%
American Indian		2.0%
Asian	1.4%	2.8%
Black or African-American	46.6%	40.2%
Native Hawaiian or Pacific Islander	0.0%	0.4%
White or Caucasian	7.8%	49.2%
Other Race	14.2%	18.5%
Declined / Unavailable		

FKC Rockfish

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	49.4%	50.5%
Male	50.6%	49.5%
Unknown		
64 and Younger	57.8%	86.7%
65 and Older	42.2%	13.3%
American Indian		2.0%
Asian	2.4%	2.8%
Black or African-American	75.9%	40.2%
Native Hawaiian or Pacific Islander	3.6%	0.4%
White or Caucasian	8.4%	49.2%
Other Race	9.6%	18.5%
Declined / Unavailable		

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 72, the applicant states it has no such obligation.

In Section L, page 72, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights equal access complaints have been filed against its facilities.

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.

- (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, pages 72, the applicant projects the following payor mix during the second full fiscal year of operation following project completion of the project, as illustrated in the following table:

FKC Rockfish Projected Payor Mix, Second Project Year

PAYOR SOURCE	# OF PT.S	% OF TOTAL
Self-Pay	0.7	1.60%
Insurance*	2.4	5.66%
Medicare*	30.8	71.59%
Medicaid*	3.6	8.35%
Other^	5.5	12.80%
Total	43.1	100.00%

*Includes any managed care plans

^On page 70 the applicant states "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 1.6% of services will be provided to self-pay patient, 71.59% to Medicare patients; and 8.35% to Medicaid patients.

On pages 72-73 the applicant provides the assumptions and methodology it uses to project payor mix during the second full fiscal year of operation following project completion. The projected payor mix is reasonable and adequately supported because it is based on the historical payor source data from the two dialysis facilities from which the dialysis stations are proposed to be relocated.

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.

- (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 74, the applicant adequately describes the range of means by which patients will have access to the proposed services and provides supporting documentation in Exhibit L-4.

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.

- (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 15-station dialysis facility by relocating no more than six dialysis stations from FMC West Fayetteville and no more than nine dialysis stations from FKC Rockfish.

In Section M, page 75, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.2. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- The applicant is a current provider of dialysis services in Cumberland County and currently partners with local community colleges for training programs.
- Exhibit M-2 provides a copy of a letter from the applicant to Fayetteville Technical Community College that proposes the inclusion of FKC Spring Lake in the nursing students' clinical rotations.

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 15-station dialysis facility by relocating no more than six dialysis stations from FMC West Fayetteville and no more than nine dialysis stations from FKC Rockfish.

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

Table 9A on page 121 of the 2025 SMFP shows six existing or approved dialysis facilities in Cumberland County as shown in the following table:

FACILITY	# STATIONS	# PATIENTS	% UTILIZATION
Fayetteville Kidney Center	57	164	71.93%
FMC Dialysis Services North Ramsey	54	128	59.26%
FMC Dialysis Services South Ramsey	56	158	70.54%
FMC Services of West Fayetteville	40	137	85.63%
FKC Hope Mills	0	0	0.00%
FKC Rockfish	25	88	88.00%

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 76, the applicant states:

“The 2025 SMFP reports that there are currently five operational dialysis facilities with in-center dialysis stations within Cumberland County and one facility that is currently under development. All of these facilities are owned/operated by Fresenius Medical Care. With this application, the applicant seeks the opportunity to continue providing dialysis care and treatment to the patients of the area who have expressed their desire to receive dialysis care and treatment at FKC Spring Lake Dialysis.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 77, 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 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 C, F, K, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 77, 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.”

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 77, the applicant states:

“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 Section 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

The applicant proposes to develop a new 15-station dialysis facility by relocating no more than nine dialysis stations from FMC West Fayetteville and no more than 9 dialysis stations from FKC Rockfish.

On Form O in Section Q, 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 132 existing or approved kidney disease treatment facilities located in North Carolina.

In Section O, page 82, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents resulting in an Immediate Jeopardy violation that occurred in any BMA facilities. After reviewing and considering information provided by the applicant and publicly available data considering the quality of care provided at all 132 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 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.3, page 33 and Section Q, Form C, the applicant projects 42.5 in-center patients will be served by the proposed facility by the end of the first operating year, which is 2.83 patients per station per week $[42.5 / 15 = 2.83]$. Projected utilization of 2.83 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.
- (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 the assumptions following Form C in Section Q, the applicant provides the assumptions and methodology it used to project utilization. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.