

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: December 5, 2025

Findings Date: December 5, 2025

Project Analyst: Chalice L. Moore

Co-Signer: Mike McKillip

Project ID #: F-12697-25

Facility: Cornelius Home Dialysis

FID #: 250854

County: Mecklenburg

Applicant: FMS Cornelius Home, LLC

Project: Develop a new dialysis facility dedicated to home hemodialysis and peritoneal dialysis training and support by relocating no more than 2 dialysis stations from FKC Mallard Creek

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

FMS Cornelius Home, LLC (hereinafter referred to as “the applicant” or Cornelius Home Dialysis) proposes to develop a new dialysis facility dedicated to home hemodialysis (HHD) and peritoneal dialysis (PD) training and support by relocating no more than two stations from FKC Mallard Creek.

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 or offer a new institutional health service for which there are any applicable 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- (2) Repealed effective July 1, 1987.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 dialysis facility dedicated to home hemodialysis (HHD) and peritoneal dialysis (PD) training and support by relocating no more than two stations from FKC Mallard Creek.

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

The proposed project is for a new facility, therefore there is no historical patient origin data. The following table illustrates the historical patient origin for the existing dialysis stations that will be relocated from FKC Mallard Creek to the new proposed facility:

FKC Mallard Creek Dialysis Historical Patient Origin Last Full FY CY 2024						
County	# of IC Patients	% of Total	# of HH Patients	% of Total	# of PD Patients	% of Total
Mecklenburg	42.0	82.4%				
Alleghany	1.0	2.0%				
Cabarrus	3.0	5.9%				
Davidson	1.0	2.0%				
Iredell	1.0	2.0%				
Lee	1.0	2.0%				
Union	1.0	2.0%				
South Carolina	1.0	2.0%				
Total	51.0	100.0%				

Source: Section C, page 24

The applicant has also provided, for reference, historical patient origin data for INS Freedom Dialysis and INS Victory Home. These facilities currently provide training and support services for existing home dialysis patients in Mecklenburg County and surrounding areas.

INS Freedom Dialysis Historical Patient Origin Last Full FY CY 2024						
County	# of IC Patients	% of Total	# of HH Patients	% of Total	# of PD Patients	% of Total
Mecklenburg			32.0	71.1%	52.0	78.8%
Cabarrus			1.0	2.2%	3.0	4.5%
Davidson			1.0	2.2%	1.0	1.5%
Gaston			5.0	11.1%	5.0	7.6%
Iredell			2.0	4.4%	1.0	1.5%
Lincoln			1.0	2.2%	1.0	1.5%
South Carolina			3.0	6.7%	3.0	4.5%
Total			45.0	100.0%	66.0	100.0%

Source: Section C, page 24

INS Victory Home Dialysis Historical Patient Origin Last Full FY CY 2024						
County	# of IC Patients	% of Total	# of HH Patients	% of Total	# of PD Patients	% of Total
Mecklenburg			26.0	81.3%	37.0	88.1%
Cabarrus			3.0	9.4%	2.0	4.8%
Gaston			1.0	3.1%		
Lincoln					1.0	2.4%
Union					2.0	4.8%
South Carolina			2.0	6.3%		
Total			32.0	100.0%	42.0	100.0%

Source: Section C, page 25

The following table illustrates projected patient origin for the proposed Cornelius Home Dialysis facility.

Cornelius Home Dialysis Projected Patient Origin Second Full FY CY 2029						
County	# of IC Patients	% of Total	# of HH Patients	% of Total	# of PD Patients	% of Total
Mecklenburg			3.3	62.3	14.3	100.0
Iredell			1.0	18.8		
Lincoln			1.0	18.8		
Total			5.3	100.0	14.3	100.0

Source: Section C, page 23

In Section C, pages 25-30, the applicant provides the assumptions and methodology used to project patient origin. The applicant's assumptions are reasonable and adequately supported by letters of support from patients already dialyzing at home and have expressed an interest in transferring their care to Cornelius Home Dialysis.

Analysis of Need

In Section C, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On pages 31-33, the applicant states:

“Given the national emphasis on home dialysis, there has been a shift in referral trends within the Fresenius related dialysis facilities. Fresenius Medical Care is experiencing a larger number of referrals for home dialysis. More and more patients are being referred for home dialysis versus the traditional in-center model for dialysis patient treatment. Development of a new freestanding kidney disease treatment center in Mecklenburg County will allow the applicant to provide specialized services that are specific to home therapy patients...BMA searched many areas of Mecklenburg County and has identified a suitable site for development of the new facility. The site identified for this facility is in Cornelius, North Carolina and will be accessible for the existing home dialysis patients who have expressed an interest in transferring to this facility and as well as future patients who are candidates for home dialysis and would like to train at this facility. The applicant believes this new facility will be close to a number of patients residence and therefore more convenient for dialysis.”

The information is reasonable and adequately supported based on the trend towards home therapy and the number of existing patients expressing an interest in transferring their care to the proposed facility.

Projected Utilization

Home Methodology:

In Section C, pages 29-31, and in Section Q, the applicant provides the home hemodialysis (HHD) and peritoneal dialysis (PD) projected utilization for Cornelius Home Dialysis, which is summarized as follows:

- The applicant begins with identifying the number of patients by county of patient residence and the dialysis facility where they are currently reporting to for monthly follow-up visits.

Facility	Patient Residence Zip Code						Totals
	28078	28269	28262	28117	28036	28037	
INS Freedom	1	9	3	1	1	1	16
INS Victory		1	1				2
Total	1	6	2	1	1	1	18

- The applicant projects growth of the Mecklenburg County patient population at Cornelius Home Dialysis using a 5.0% growth rate. The basis for this growth rate is the Mecklenburg County home dialysis patient population growth at INS Freedom Dialysis and INS Victory Home as described above.

- Iredell and Lincoln County are contiguous to Mecklenburg County; thus, it is not unreasonable for patients who reside in these counties to travel to Mecklenburg County once a month for a follow-up visit as either an existing home dialysis patient or as a new home dialysis patient upon completion of their home dialysis training. The applicant will not project growth of the Iredell and Lincoln County patient population, but these patients will be added to future projections at specific points of time.
- The two stations are being relocated from FKC Mallard Creek to the new Cornelius Home Dialysis and that are projected to be certified at the new facility on December 31, 2027.
 - Operating Year 1 is the period from January – December 31, 2028
 - Operating Year 2 is the period from January – December 31, 2029

	HHD	PD
Begin with the Mecklenburg County patient population who have signed letters of support to transfer their care to the facility upon project completion on December 31, 2027.	2.0	8.0
Project the Mecklenburg County patient population forward one year to December 31, 2028.	$2.0 \times 1.050 = 2.1$	$8.0 \times 1.050 = 8.4$
Add the patients from other counties. This is the projected ending census for Operating Year 1.	$2.1 + 2.0 = 4.1$	
Project the Mecklenburg County patient population forward one year to December 31, 2029.	$2.1 \times 1.050 = 2.2$	$8.4 \times 1.050 = 8.8$
Add the patients from other counties. This is the projected ending census for Operating Year 2.	$2.2 + 2.0 = 4.2$	

Source: Section C, page 30

The applicant, based upon the above calculations, projects the following number of patients for operating years one and two, provided in the table below:

Cornelius Home Dialysis	Operating Year 1	Operating Year 2
Home Hemodialysis	5.2	5.3
Peritoneal Dialysis	13.7	14.3

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

- The applicant accounts for PD patients in adjacent counties who currently receive services in Mecklenburg County, adding them to the facility census at appropriate points in time.
- The applicant’s projected utilization in the first two years of operation is based on the historical growth rate for the Mecklenburg County home dialysis patient population currently treated at INS Freedom Dialysis and INS Victory Home as described above.

Access to Medically Underserved Groups

In Section C, pages 35 and 36, the applicant states:

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

Medically Underserved Groups	Estimated Percentage of Total Patients during the Second Full Fiscal Year
Low-income persons	27.5%
Racial and ethnic minorities	79.1%
Women	42.2%
Persons with Disabilities	2.8%
Persons 65 and older	16.1%
Medicare beneficiaries	65.4%
Medicaid recipients	20.41%

Source: Section C, page 36

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the applicant’s history of providing services to medically underserved groups and its statement that these groups will continue to have access to its 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 dialysis facility dedicated to home hemodialysis (HHD) and peritoneal dialysis (PD) training and support by relocating no more than two stations from FKC Mallard Creek.

On page 41, the applicant provides a table showing the stations that will be relocated from FKC Mallard Creek to Cornelius Home Dialysis.

FKC Mallard Creek	
	Mecklenburg
1. Total number of existing, approved, and proposed dialysis stations as of the application deadline	18
2. Number of existing dialysis stations to be reduced, relocated or eliminated in the proposal	2
3. Total number of dialysis stations upon completion of this project and all other projects involving this facility	16

Source: Section D, page 41

In Section D, page 43, the applicant explains why it believes the needs of the population presently utilizing the services to be relocated will be met following completion of the project.

The applicant states,

“The relocation of two dialysis stations from FKC Mallard Creek to Cornelius Home 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.”

In Section D, pages 41-43, the applicant provides its methodology and assumptions for projecting utilization for FKC Mallard Creek following relocation of two stations to Cornelius Home Dialysis as follows:

1. The applicant will project growth of the patient population at the facility through December 31, 2027, the date stations are projected to be relocated to Cornelius Home Dialysis.

2. As of December 31, 2024, FKC Mallard Creek was serving a total of 42 Mecklenburg County in-center dialysis patients. This information was reported on the 2024 ESRD Data Collection form that was submitted to Healthcare Planning in February 2025 and is shown on the Chapter 9: Dialysis Data by County of Patient Origin Report for the Proposed 2026 SMFP.
3. FKC Mallard Creek is a newer facility that has significantly grown since it began operations in 2022. Specifically, the Mecklenburg County patient population at the facility has grown from 14 patients as of December 31, 2022, to 42 patients as of December 31, 2024. The Five Year Average Annual Change Rate (5-Year AACR) published in the 2025 SMFP for Mecklenburg County is 0.0%. The applicant projects growth of the Mecklenburg County patient population using a 5.0% growth rate based on the facility's historical experience since it began operations in 2022, which is less than the actual growth the facility has experienced.
4. The facility was also serving one in-center dialysis patient residing in Alleghany County, three in-center dialysis patients residing in Cabarrus County, one in-center dialysis patient each residing in Davison, Iredell, Lee, and Union County and one in-center dialysis patient residing in South Carolina. Cabarrus, Iredell, Union County and South Carolina are all contiguous to Mecklenburg County. It is reasonable to expect patients residing in these areas would continue dialysis at a facility in Mecklenburg County as a function of patient choice. The applicant will not project growth of this patient population, but these patients will be added to projections of future patient populations at appropriate points in time. The applicant assumes that the Alleghany, Davidson and Lee County patients were transient patients and will not be carried forward in any future patient projections.
5. The stations being relocated from FKC Mallard Creek are projected to be certified at the new Cornelius Home Dialysis facility on December 31, 2027.
 - Operating Year 1 is the period from January 1- December 31, 2028
 - Operating Year 2 is the period from January 1- December 31, 2029

FKC Mallard Creek	
Begin with the Mecklenburg County patient population as of December 31, 2024.	42.0
Project the Mecklenburg County patient population forward one year to December 31, 2025.	$42.0 \times 1.050 = 44.1$
Add the six in-center patients from other counties and South Carolina. This is the projected ending census for Interim Year 1.	$44.1 + 6.0 = 50.1$
Project the Mecklenburg County patient population forward one year to December 31, 2026.	$44.1 \times 1.050 = 46.3$
Add the six in-center patients from other counties and South Carolina. This is the projected ending census for Interim Year 2.	$46.3 + 6.0 = 52.3$
Project the Mecklenburg County patient population forward one year to December 31, 2027.	$46.3 \times 1.050 = 48.6$
Add the six in-center patients from other counties and South Carolina. This is the projected ending census for Interim Year 3.	$48.6 + 6.0 = 54.6$
Project the Mecklenburg County patient population forward one year to December 31, 2028.	$48.6 \times 1.050 = 51.1$
Add the six in-center patients from other counties and South Carolina. This is the projected ending census for Operating Year 1.	$51.1 + 6.0 = 57.1$
Project the Mecklenburg County patient population forward one year to December 31, 2029.	$51.1 \times 1.050 = 53.6$
Add the six in-center patients from other counties and South Carolina. This is the projected ending census for Operating Year 2.	$53.6 + 6.0 = 59.6$

The applicant states FKC Mallard Creek is projected to have an in-center census of 54.6 patients as of December 31, 2027. The utilization is calculated as the following:

54.6 patients dialyzing on 16 stations (54.6/16) = 3.41 patients per station per week or a utilization rate of 85.34%.

Access to Medically Underserved Groups

In Section D, page 43, the applicant states the relocation of two dialysis stations from FKC Mallard Creek to Cornelius Home 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 the needs of medically underserved groups will be adequately met following completion of the project based on FKC Mallard Creek history of providing care to these groups and its statements assuring continued access.

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, eliminate 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.

C

The applicant proposes to develop a new dialysis facility dedicated to home hemodialysis (HHD) and peritoneal dialysis (PD) training and support by relocating no more than two stations from FKC Mallard Creek.

In Section E, page 46, the applicant states there were no alternatives considered and explains why there were no alternatives available.

The applicant states,

“The applicant truly has only one alternative: apply or not apply... The applicant seeks to develop this facility to better serve the ESRD patient population of Mecklenburg County choosing home dialysis. Freestanding home therapy facilities have a specific emphasis on home dialysis patients. The applicant believes that this increased emphasis will result in more patients choosing home dialysis which results in an improved quality of life, quality of care, and patient outcomes by offering a more convenient alternative for dialysis treatment over the traditional in-center model of traveling to an in-center clinic 3 x a week. ... BMA and the MNA physicians both recognize the importance of home dialysis and are committed to increasing home therapy penetration in Mecklenburg County, especially given the significant growth in the HHD patient population within the last year. This growth is attributed to BMA home therapy initiatives and the MNA physicians who have been serving CKD and ESRD patients in Mecklenburg County for many years. The practice brings together the collaborative efforts of a team of very qualified nephrologists who provide care for dialysis patients in western North Carolina. The home therapy initiatives described in Section C Question 3 of this application demonstrate our continued emphasis on home therapy as the preferred modality of treatment for our dialysis patients. These initiatives are aligned with the 2019 Executive Order on Advancing American Kidney Health and is strong evidence that home dialysis will continue to grow in the future, that greater capacity for home training and support is needed, which encourages greater rates of home dialysis to improve the quality of life and care for dialysis patients.”

The applicant adequately demonstrates the reason there were no alternatives to the alternative proposed and that the relocation of the two stations is the most effective alternative to meet the need based on the following:

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 1. FMS Cornelius Home, LLC (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**

2. **The certificate holder shall relocate no more than two in-center dialysis stations from FKC Mallard Creek to establish a freestanding dialysis facility dedicated to home hemodialysis and peritoneal dialysis training and support to be known as Cornelius Home Dialysis.**
 3. **Upon the completion of this project, the certificate holder shall take the necessary steps to decertify two in-center dialysis stations at FKC Mallard Creek for a total of no more than 16 in-center dialysis stations at FKC Mallard Creek upon completion of the project.**
 4. **The certificate holder shall install plumbing and electrical wiring through the walls for no more than two home hemodialysis stations.**
 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 dialysis facility dedicated to home hemodialysis (HHD) and peritoneal dialysis (PD) training and support by relocating no more than two stations from FKC Mallard Creek.

Capital and Working Capital Costs

In Section Q, Form F.1a Capital Cost, page 99, the applicant projects the total capital cost of the project, as summarized below.

Projected Capital Cost	Total
Construction/Renovation Contract	\$1,280,668
Architect/Engineering Fees	\$114,744
Non-Medical Equipment	\$40,350
Furniture	\$102,782
Other: Generator	\$46,785
Other: Contingency	\$63,747
Total Capital Cost	\$1,649,076

In Section Q, pages 100, 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 construction estimates provided by an in-house real estate and construction team and its experience as one of the longest providers of dialysis services in the state.

In Section F, page 48, the applicant states there will be start-up costs of \$193,116 and initial operating costs of \$793,414 for total working capital of \$986,530. On pages 49-51, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the proposed working capital needs are based on reasonable and adequately supported assumptions based on the following:

- Start-up costs would include purchasing supplies, hiring staff, and training staff.
- The applicant estimates that the initial operating period would be six months to allow for cash in-flow to exceed cash out-flow.

Availability of Funds

In Section F, page 51, the applicant states it will fund both the capital cost and the working capital cost with corporate accumulated reserves of Fresenius Medical Care Holdings, Inc., a majority owner of FMS Cornelius Home, LLC. FMS Cornelius Home, LLC is a joint venture between Bio-Medical Applications of North Carolina, Inc., and Metrolina Nephrology Associates, P.A. In Exhibit F-2, the applicant provides a September 15, 2025 letter signed by the VP Corporate Tax North America for Fresenius Medical Care Holdings, Inc. confirming the proposal capital cost of the project, the availability of sufficient funds for both the capital and working capital costs and committing the funds to this project development.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the letter of commitment provided in Exhibit F-2 of the application and Fresenius Medical Care Holdings, Inc. financial statements as of March 31, 2025.

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, pages 108-113, the applicant projects that operating expenses will exceed revenues in the first and second full fiscal years following completion of the project, as shown in the table below.

Cornelius Home Dialysis	1st Full FY CY2028	2nd Full FY CY2029
Total # of Treatments	2,723	2,845
Total Gross Revenues (Charges)	\$17,131,651	\$17,895,127
Total Net Revenue	\$1,416,427	\$1,480,642
Average Net Revenue per Treatment	\$6291	\$6290
Total Operating Expenses (Costs)	\$1,586,828	\$1,620,416
Average Operating Expense per Treatment	\$583	\$570
Net Income	(\$170,402)	(\$139,774)

In Section Q, page 104, the applicant states,

“Fresenius Medical Care is aware that the Cornelius Home Dialysis facility will be operating in a financial loss position for the first two operating years. This is solely due to the cost of constructing a new facility from the ground up. The applicant will routinely search for existing rentable space which would be suitable for renovation and use for the dialysis facility. Finding an existing structure eliminates the cost of building new space. Renovations can be accomplished much more cost effectively than building a new structure. However, in an effort to develop the new facility in the desired location, the applicant elected to have space constructed by a developer 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 Cornelius Home Dialysis facility. Exhibit F-3 includes the Fresenius Medical Care Holdings, Inc. and Subsidiaries Consolidated Financial Statements for Quarter One of 2025, which will show that Fresenius Medical Care Holdings, Inc. has the financial means to absorb the financial losses of the Cornelius Home Dialysis facility until it returns to a profitable status.”

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q, pages 103-104. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant’s projections of Bad Debt are based on the historical performance of INS Freedom and INS Victory home therapy programs.
- Contractual adjustments are calculated by payor class and modality for each year and is based on the average contractual adjustments at INS Freedom and INS Victory Home.
- 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 and working capital costs 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 dialysis facility dedicated to home hemodialysis (HHD) and peritoneal dialysis (PD) training and support by relocating no more than two stations from FKC Mallard Creek.

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 Mecklenburg County. Facilities may serve residents of counties not included in their service area.

In Section G, page 54, the applicant states that there are two existing freestanding home therapy facilities in Mecklenburg County that offer training and support services, INS Freedom Dialysis and INS Victory Home.

Mecklenburg County			
Facility	Certified Stations as of 12/31/2024	Home Hemodialysis Patients 12/31/2024	Peritoneal Patients 12/31/2024
INS Freedom Dialysis	9	45	66
INS Victory Home	7	32	42
Total	16	77	108

In Section G, page 55, the applicant explains why it believes its proposal would not result in the necessary duplication of existing or approved dialysis services in Mecklenburg County. The applicant states:

“The applicant is not proposing to develop new dialysis stations by this proposal. The applicant proposes to relocate existing certified dialysis stations within Mecklenburg County. As described in Section C of this application, the Mecklenburg County home dialysis patient population has grown, specifically the home hemodialysis patient population, and this growth is projected to continue. The addition of a new facility in the county emphasizing home dialysis training and support services will serve to meet the needs of the county’s growing home dialysis patient population as a result of increased referrals made by the admitting nephrologists. The proposed project will relocate existing stations within the same county which is not an unnecessary duplication of the same existing or approved health services located in the service area.”

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 Mecklenburg County.
- The applicant adequately demonstrates that the proposed relocation of the existing certified dialysis stations is needed in Mecklenburg County.

Conclusion

The Agency reviewed the:

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

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

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

C

The applicant proposes to develop a new dialysis facility dedicated to home hemodialysis (HHD) and peritoneal dialysis (PD) training and support by relocating no more than two stations from FKC Mallard Creek.

On Form H referenced in Section Q, the applicant provides the projected staffing for the proposed services for the first two operating years, as illustrated in the following table.

Position	1 st FFY	2 nd FFY
	CY2028	CY2029
Administrator (FMC Clinic Manager)	1.00	1.00
Home Training Nurses	2.00	2.00
Technicians (PCT)	3.00	3.00
Dietician	0.35	0.35
Social Worker	0.35	0.35
Maintenance	0.45	0.45
Administration /Business Office	0.50	0.50
Other (FMC Director of Operations)	0.33	0.33
Other (FMC Chief Technician)	0.25	0.25
Other (FMC In-Service)	0.17	0.17
Total	8.40	8.40

Source: Section Q, Form H

The assumptions and methodology used to project staffing are provided in Section Q, page 111. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.4 in Section Q, page 107. In Section H, pages 56-57, 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, in Form H Assumptions, that the number of FTE positions is a function of the number of stations available and the patient census to ensure quality care and maximize cost effectiveness.
- 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 dialysis facility dedicated to home hemodialysis (HHD) and peritoneal dialysis (PD) training and support by relocating no more than two stations from FKC Mallard Creek.

Ancillary and Support Services

In Section I, page 58, the applicant identifies the necessary ancillary and support services for the proposed services. In Section I, pages 58-63, 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 because the applicant describes the structure in place at both the corporate level and the facility level for providing the necessary ancillary and support services.

Coordination

In Section I, page 63, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit H. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant's parent company, Fresenius Medical Care, has existing relationships with local health care and social service providers.
- The applicant will be working with the Metrolina Nephrology Associates physicians who will provide referrals to the facility and will also have admitting and rounding privileges at the facility.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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

- (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 dialysis facility dedicated to home hemodialysis (HHD) and peritoneal dialysis (PD) training and support by relocating no more than two stations from FKC Mallard Creek.

In Section K, page 66, the applicant states that the project involves constructing 3,731 square feet of new space. Line drawings are provided in Exhibit K-2.

On page 13, the applicant identifies the proposed site and on pages 68-69 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 project based on the applicant's representations and supporting documentation.

On page 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 will rely upon the extensive experience of the Fresenius Medical Care Real Estate and Construction Services team to develop anticipated project costs for this proposal. The RECS staff utilize a national database to ensure the project costs are reasonable and accurate. The applicant has relied upon this format for development of multiple CON related projects in North Carolina. Fresenius estimates are realistic and reasonable.

On page 67, 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:

- Development of two dialysis stations at a freestanding home therapy facility will ensure convenient access to home dialysis care for patients of the area. The costs of development are not passed on to the patient. Rather, the costs of relocation are borne by the applicant. This project will not increase costs or charges to the public for the proposed services..

On pages 67-68, 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 71, the applicant states that this is a new facility and does not have any historical information to report. The applicant does provide the historical payor

mix during CY2024 for its existing services at FKC Mallard Creek, INS Freedom Dialysis, and INS Victory Home as shown in the tables below.

Primary Payor Source at Admission	FKC Mallard Creek					
	In-center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-Pay	4.2	8.22%				
Insurance*	41.0	80.45%				
Medicare*	2.7	5.34%				
Medicaid*	2.8	5.56%				
Other	0.2	0.43%				
Total	51.0	100.00%				

Primary Payor Source at Admission	INS Freedom Dialysis					
	In-center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-Pay			0.6	1.31%	1.1	1.65%
Insurance*			13.0	28.87%	24.4	36.99%
Medicare*			27.7	61.52%	35.8	54.25%
Medicaid*			2.7	5.98%	1.7	2.56%
Other			1.0	2.32%	3.0	4.55%
Total			45.0	100.00%	66.0	100.0%

Primary Payor Source at Admission	INS Victory Home					
	In-center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-Pay				0.00%	0.6	1.50%
Insurance*			3.8	11.82%	11.7	27.78%
Medicare*			23.2	72.55%	26.2	62.49%
Medicaid*			1.8	5.52%	2.6	6.12%
Other			3.2	10.11%	0.9	2.12%
Total			32.0	100.00%	42.0	100.00%

In Section L, pages 72-73, the applicant states that this is a new facility and does not have any historical information to report. The applicant does provide the historical comparison of the population served for its existing services at FKC Mallard Creek, INS Freedom Dialysis, and INS Victory Home as shown in the tables below:

FKC Mallard Creek	Last Full Operating Year	
	Percentage of Total Patients Served	Percentage of the Population of the Service Area
Female	18.4%	51.7%
Male	81.6%	48.3%
Unknown		
64 and Younger	80.7%	87.7%
65 and Older	19.3%	12.3%
American Indian		1.0%
Asian	1.8%	6.7%
Black or African American	36.8%	32.8%
Native Hawaiian or Pacific Islander		0.1%
White or Caucasian	3.5%	56.6%
Other Race		
Declined/ Unavailable		

INS Freedom Dialysis	Last Full Operating Year	
	Percentage of Total Patients Served	Percentage of the Population of the Service Area
Female	36.8%	51.7%
Male	63.2%	48.3%
Unknown		
64 and Younger	90.4%	87.7%
65 and Older	9.6%	12.3%
American Indian	1.8%	1.0%
Asian	0.9%	6.7%
Black or African American	80.7%	32.8%
Native Hawaiian or Pacific Islander		0.1%
White or Caucasian	15.8%	56.6%
Other Race	0.9%	18.6%
Declined/ Unavailable		

INS Victory Home	Last Full Operating Year	
	Percentage of Total Patients Served	Percentage of the Population of the Service Area
Female	41.2%	51.7%
Male	58.8%	48.3%
Unknown		
64 and Younger	79.8%	87.7%
65 and Older	20.2%	12.3%
American Indian		1.0%
Asian	3.5%	6.7%
Black or African American	53.5%	32.8%
Native Hawaiian or Pacific Islander		0.1%
White or Caucasian	24.6%	56.6%
Other Race	3.5%	18.6%
Declined/ Unavailable		

Conclusion

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 74, the applicant states it has no such obligation.

The applicant further states during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against the facility identified in Section A, Question 4.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is confirming 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 74, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

Cornelius Home Dialysis Projected Payor Mix CY2029						
Payment Source	IC		HH		PD	
	# of Patients	% of Patients	# of Patients	% of Patients	# of Patients	% of Patients
Self-Pay					0.1	1.57%
Insurance*			0.9	20.34%	3.0	32.89%
Medicare*			2.9	67.03%	5.4	58.37%
Medicaid*			0.2	5.75%	0.4	4.34%
Misc. (including VA)			0.3	6.21%	0.3	3.33%
Total			4.3	100.00%	9.3	100.00%

Including any managed care plans
 Source: Section L, page 77

On pages 74-75, the applicant provides the assumptions and methodology it uses to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical experience of the existing dialysis facilities from which HHD and PD patients will transfer from.

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 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, pages 75-76, 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 dialysis facility dedicated to home hemodialysis (HHD) and peritoneal dialysis (PD) training and support by relocating no more than two stations from FKC Mallard Creek.

In Section M, page 77, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M.2. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- The applicant provides documentation for their Healthcare Professional Training Agreement/Outreach initiatives as well as a confirmation letter expressing their intent to extend their services as a clinical training site for nursing students of a community college in the area.
- The applicant states it routinely receives requests for information from individual students or program directors. The Center Manager will provide discussion of ESRD and dialysis for students, after which time the students may observe, tour the facility and talk with patients.

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 dialysis facility dedicated to home hemodialysis (HHD) and peritoneal dialysis (PD) training and support by relocating no more than two stations from FKC Mallard Creek.

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 Mecklenburg County. Facilities may serve residents of counties not included in their service area.

Mecklenburg County			
Facility	Certified Stations as of 12/31/2024	Home Hemodialysis Patients 12/31/2024	Peritoneal Patients 12/31/2024
INS Freedom Dialysis	9	45	66
INS Victory Home	7	32	42
Total	16	77	108

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 78, the applicant states:

“The applicant does not expect this proposal to have any effect on the competitive climate in Mecklenburg 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 and growth of that population as described in Section C of this application. The proposed project will relocate existing stations within Mecklenburg County to ensure that patients choosing to receive home dialysis in the service area will continue to have adequate access to high quality home dialysis care.

The draft 2026 SMFP reports there are currently two home training dialysis facilities in Mecklenburg County, all of which are owned/operated by Fresenius Medical Care. With this application, the applicant seeks the opportunity to continue providing home dialysis training and support services to ESRD patients in the service area who desire home dialysis training and support services at a BMA affiliated facility in Mecklenburg County.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 79, the applicant states:

“This is a proposal to relocate two existing certified dialysis stations from FKC Mallard Creek to a new freestanding dialysis facility, Cornelius Home Dialysis, that will be exclusively dedicated to HHD and PD training and support services. Approval of this application address the national emphasis to home therapy services in Mecklenburg County. 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 79, 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 Section B of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 79, 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 All Fresenius Medical Care related facilities in North Carolina have a history of providing dialysis services to the underserved populations of North Carolina. The Form O identifies all Fresenius related operational and/or CON approved facilities across North Carolina. Each of those 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 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 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.

The applicant proposes to develop a new dialysis facility dedicated to home hemodialysis (HHD) and peritoneal dialysis (PD) training and support by relocating no more than two stations from FKC Mallard Creek.

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 133 existing or approved kidney disease treatment facilities located in North Carolina.

In Section O, page 84, 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 of these facilities. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all 125 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.

SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES

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.*

-NA- The applicant does not propose to develop a new dialysis facility for in-center hemodialysis services.

(b) *An applicant proposing to increase the number of in-center 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 full fiscal year of operation following certification of the additional stations.

-NA- The applicant is not proposing to increase the number of in-center dialysis stations.

(c) *An applicant proposing to establish a new dialysis facility dedicated to home hemodialysis or peritoneal dialysis training shall document the need for the total number of home hemodialysis stations in the facility based on training six home hemodialysis patients per station per year as of the end of the first full fiscal year of operation following certification of the facility.*

-C- This proposal is to develop a new dialysis facility dedicated to HHD and PD training and support services by relocating two existing dialysis stations from FKC Mallard Creek. In Section C, page 38, the applicant projects it will train 13.4 home hemodialysis patients on two stations for an average of six home hemodialysis patients per station per year by the end of the first fiscal year of operation following certification of the facility.

(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) *The applicant shall provide the assumptions and methodology used for the projected utilization required by this Rule.*

-C- In Section C, page 38, the applicant provides the assumptions and methodology used to project utilization of the proposed facility by home hemodialysis patients.