

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: February 24, 2025

Findings Date: February 24, 2025

Project Analyst: Yolanda W. Jackson

Co-Signer: Micheala Mitchell

Project ID #: L-12555-24

Facility: Nash County Home

FID #: 240784

County: Nash

Applicant(s): FMS Boice-Willis Home, LLC

Project: Relocate two existing dialysis stations and entire Home Therapy Program from FMC South Rocky Mount to a new free-standing dialysis facility, dedicated exclusively to Home Hemodialysis (HHD) and Peritoneal (PD)

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 Boice-Willis Home, LLC doing business as Nash County Home (hereinafter referred to as “the applicant”), proposes to relocate two existing dialysis stations and the entire home therapy program from FMC South Rocky Mount in Nash County to a new free-standing dialysis facility, Nash County Home, in Nash County that will be exclusively dedicated to home hemodialysis (HHD) and peritoneal dialysis (PD) training and support services. Fresenius Medical Care is the parent company of FMS Boice-Willis Home, LLC.

The applicant does not propose to:

- Develop any beds or services for which there is a need determination in the 2024 State Medical Facilities Plan (SMFP)

- Acquire any medical equipment for which there is a need determination in the 2024 SMFP
- Offer a new institutional health service for which there are any policies in the 2024 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- (2) Repealed effective July 1, 1987.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 relocate no more than two dialysis stations and the entire home therapy program from FMC South Rocky Mount to a new dialysis facility dedicated to home hemodialysis (HHD) and peritoneal dialysis (PD) training and support services.

Patient Origin

On page 113, the 2024 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.*” Both Nash County Home and FMC South Rocky Mount are located in Nash County. Thus, the service area for this facility consists of Nash County. Facilities may also serve residents of counties not included in their service area.

The applicant proposes to relocate no more than two dialysis stations and the entire home therapy program from FMC South Rocky Mount to a new dialysis facility dedicated to home hemodialysis (HHD) and peritoneal dialysis (PD) training and support services; therefore, historical patient data does not exist. In Section C, page 23, the applicant provides the historical (CY2023) patient origin for FMC South Rocky Mount, as summarized in the following table.

The following tables illustrates historical and projected patient origin.

County	FMC South Rocky Mount – Historical Patient Origin					
	Last Full FY 01/01/2023 – 12/31/2023					
	# of In-Center Patients	% of Total	# of Home Hemodialysis Patients	% of Total	# of Peritoneal Dialysis Patients	% of Total
Nash	42.0	62.7%	6.0	66.7%	25.0	64.1%
Edgecombe	16.0	23.9%	3.0	33.3%	9.0	23.1%
Halifax	4.0	6.0%	0.0	0.0%	5.0	12.8%
Wilson	5.0	7.5%	0.0	0.0%	0.0	0.0%
Total	67.0	100.0%	9.0	100.0%	39.0	100.0%

Source: Section C, page 23.

Note: Totals may not foot due to rounding.

In Section C.3, page 24, the applicant provides the projected, home hemodialysis (HHD), and peritoneal dialysis (PD) patient origin for Nash County Home for the second full operating year following project completion (CY2028), as summarized in the following table.

Nash County Home – Projected Patient Origin				
Second Full FY 01/01/2028 to 12/31/2028				
County	Hemodialysis		Peritoneal Dialysis	
	# of HHD Patients	% of Total	# of PD Patients	% of Total
Nash	6.5	62.4%	27.1	61.8%
Edgecombe	3.9	37.6%	11.8	26.8%
Halifax	0.0	0.0%	5.0	11.4%
Wilson	0.0	0.0%	0.0	0.0%
Total	10.4	100.0%	43.9	100.0%

Source: Section C, page 24.

Note: Totals may not foot due to rounding.

Analysis of Need

In Section C, pages 31-32, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

- The applicant’s physician partners are referring more patients to home dialysis.
- More patients are choosing home dialysis because the patients can dialyze from the comfort of home and they do not have the burden of traveling three times a week for dialysis treatment.
- As of December 31, 2023, FMC South Rocky Mount has seen a 20% increase in the number of home dialysis patients from the prior year.

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

- There was an increase of 20% in the number of home dialysis patients between December 31, 2022, and December 31, 2023.
- The proposed project would allow for improved access to home dialysis training and support services for the residents of Nash County and surrounding areas.

Projected Utilization

In Section C.3, pages 29-30, and Section Q, pages 97-98, the applicant provides the calculations used to project the Nash County and Edgecombe County patient utilization at the proposed Nash County Home facility, as illustrated in the following table:

	HHD Projections	PD Projections
The applicant begins with Nash County home dialysis patient population dialyzing at FMC South Rocky Mount on December 31, 2023.	6	25
Project the Nash County patient population forward one year to December 31, 2024, using a 1.6% growth rate based on the Nash County 5-Year Average Annual Change Rate (AACR), as published in the 2024 SMFP.	$6 \times 1.016 = 6.1$	$25 \times 1.016 = 25.4$
The applicant begins with Edgecombe County home dialysis patient population dialyzing at FMC South Rocky Mount on December 31, 2023.	3	9
Project the Edgecombe County patient population forward one year to December 31, 2024, using a 5.5% growth rate based on the Edgecombe County 5-Year AACR, as published in the 2024 SMFP.	$3 \times 1.055 = 3.2$	$9 \times 1.055 = 9.5$
Add the 5 PD patients from other counties. This is the projected ending census for Interim Year 1.	$6.1 + 3.2 = 9.3$	$25.4 + 9.5 + 5.0 = 39.9$
Project the Nash County patient population forward one year to December 31, 2025, using a 1.6% growth rate.	$6.1 \times 1.016 = 6.2$	$25.4 \times 1.016 = 25.8$
Project the Edgecombe County patient population forward one year to December 31, 2025, using a 5.5% growth rate.	$3.2 \times 1.055 = 3.3$	$9.5 \times 1.055 = 10.0$
Add the 5 PD patients from other counties. This is the projected ending census for Interim Year 2.	$6.2 + 3.3 = 9.5$	$25.8 + 10.0 + 5.0 = 40.8$
Project the Nash County patient population forward one year to December 31, 2026, using a 1.6% growth rate.	$6.2 \times 1.016 = 6.3$	$25.8 \times 1.016 = 26.2$
Project the Edgecombe County patient population forward one year to December 31, 2026, using a 5.5% growth rate.	$3.3 \times 1.055 = 3.5$	$10.0 \times 1.055 = 10.6$
Add the 5 PD patients from other counties. This is the projected ending census for Interim Year 3.	$6.3 + 3.5 = 9.8$	$26.2 + 10.6 + 5.0 = 41.8$
Project the Nash County patient population forward one year to December 31, 2027, using a 1.6% growth rate.	$6.3 \times 1.016 = 6.4$	$26.2 \times 1.016 = 26.6$
Project the Edgecombe County patient population forward one year to December 31, 2027, using a 5.5% growth rate.	$3.5 \times 1.055 = 3.7$	$10.6 \times 1.055 = 11.1$

	HHD Projections	PD Projections
Add the 5 PD patients from other counties. This is the projected ending census for Operating Year 1.	$6.4 + 3.7 = 10.1$	$26.6 + 11.1 + 5.0 = 42.8$
Project the Nash County patient population forward one year to December 31, 2028. using a 1.6% growth rate.	$6.4 \times 1.016 = 6.5$	$26.6 \times 1.016 = 27.1$
Project the Edgecombe County patient population forward one year to December 31, 2028, using a 5.5% growth rate.	$3.7 \times 1.055 = 3.9$	$11.1 \times 1.055 = 11.8$
Add the 5 PD patients from other counties. This is the projected ending census for Operating Year 2.	$6.5 + 3.9 = 10.4$	$27.1 + 11.8 + 5.0 = 43.8$

In Section C pages 28-30 and Section Q, pages 96-98, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The applicant begins with the HHD and PD patient population served at FMC South Rocky Mount as of December 31, 2023.
- The applicant applies an annual growth rate of 1.6% based on the Nash County 5-Year Average Annual Change Rate (AACR), as published in the 2024 SMFP.
- Edgecombe County is contiguous with Nash County and currently 33.3% of home hemodialysis patients and 23.1% of peritoneal patients at FMC South Rocky Mount are residents of Edgecombe County. Since a significant portion of FMC South Rocky Mount patients reside in Edgecombe County, the applicant projects growth of the Edgecombe County patient population using the Edgecombe County 5-Year AACR of 5.5%, as published in the 2024 SMFP.
- The applicant does not project growth of the Halifax County patient census, but these patients will be added to projections of future patient populations at appropriate points in time. Halifax County is contiguous with Nash County. Therefore, it is reasonable to expect patients residing in Halifax County to continue dialysis at a facility in Nash County.

Projected utilization is reasonable and adequately supported for the following reasons:

- The applicant begins projections with the existing HHD and PD patients receiving home dialysis training and support at FMC South Rocky Mount in Nash County as of December 31, 2023.
- The applicant projects growth of the Nash County patient population by applying a growth rate of 1.6% based on the Nash County 5-Year AACR.
- The applicant projects growth of the Edgecombe County patient population by applying a growth rate of 5.5% based on the Edgecombe County 5-Year AACR.

Access to Medically Underserved Groups

In Section C.6, page 35, 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 health insurer.” On page 35, the applicant provides the estimated percentage for each

medically underserved group it will serve during the second operating year, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low-income persons	29.5%
Racial and ethnic minorities	74.4%
Women	45.7%
Persons with disabilities	38.0%
Persons 65 and older	44.2%
Medicare beneficiaries	82.9%
Medicaid recipients	29.5%

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 following:

- The applicant, and its parent organization, Fresenius Medical Care, have a history of providing care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or any other traditionally underserved persons.
- The applicant states that low income and medically underserved persons will continue to have access to all the services provided by Fresenius related facilities.
- The applicant's estimated percentage of total patients for each group is based upon the existing home therapy patient population of the FMC South Rocky Mount 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.

- (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.

The applicant proposes to relocate no more than two dialysis stations and the entire home therapy program from FMC South Rocky Mount to a new dialysis facility dedicated to home hemodialysis (HHD) and peritoneal dialysis (PD) training and support services.

In Section D, pages 40-45, the applicant explains why it believes the needs of the population presently utilizing the services to be relocated will be adequately met following completion of the project. The applicant states:

- The applicant is proposing to relocate two certified stations from its existing location at FMC South Rocky Mount that are currently being used for HHD training and support services to a new freestanding home therapy facility, Nash County Home, along with PD training and support services.
- The two relocated stations will continue to be used for HHD training and support services.
- The distance between the existing FMC South Rocky Mount facility where home therapy services are currently being offered and the location of the proposed freestanding home therapy facility is less than 10 miles according to Google Maps. Therefore, all patients will continue to have convenient access to dialysis care.

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

- The stations being relocated are currently being used for HHD training and these stations will continue to be used for HHD training and support services at the new freestanding dialysis facility.
- The proposed facility is less than 10 miles from the FMC South Rocky Mount facility. Therefore, the needs of the patients currently using the services will be adequately met following relocation of these services to a new freestanding facility.

In Section D, page 44, the applicant provides projected in-center utilization for FMC South Rocky Mount following relocation of two stations to the proposed facility, Nash County Home.

FMC South Rocky Mount	
The applicant begins with the Nash County patient population as of December 31, 2023.	42.0
The applicant projects the Nash County patient population forward one year to December 31, 2024.	$42 \times 1.016 = 42.7$
The applicant begins with the Edgecombe County patient population as of December 31, 2023.	16.0
The applicant projects the Edgecombe County patient population forward one year to December 31, 2024.	$16 \times 1.055 = 16.9$
The applicant adds the 9 in-center patients from other counties for the projected ending census for Interim Year 1.	$42.7 + 16.9 + 9.0 = 68.6$
The applicant projects the Nash County patient population forward one year to December 31, 2025.	$42.7 \times 1.016 = 43.4$
The applicant projects the Edgecombe County patient population forward one year to December 31, 2025.	$16.9 \times 1.055 = 17.8$
The applicant adds the 9 in-center patients from other counties for the projected ending census for Interim Year 2.	$43.4 + 17.8 + 9.0 = 70.2$
The applicant projects the Nash County patient population forward one year to December 31, 2026.	$43.4 \times 1.016 = 44.0$
The applicant projects the Edgecombe County patient population forward one year to December 31, 2026.	$17.8 \times 1.055 = 18.8$
The applicant adds the 9 in-center patients from other counties for the projected ending census for Interim Year 3.	$44.0 + 18.8 + 9.0 = 71.8$

As shown in the table above, FMC South Rocky Mount is projected to service 71.8 in-center patients on 17 stations as of December 31, 2026. Thus, the applicant projects that FMC South Rocky Mount will have a utilization rate of 108.2% [105.6%] or 4.33 [4.22] patients per station per week ($71.8 \text{ patients} / 17 \text{ stations} = 4.33 / 4 [4.22 / 4] = 1.082 [1.056]$ or 108.2% [105.6%]).¹

On page 43, the applicant provides the assumptions and methodology used to project utilization which is summarized below:

- As of December 31, 2023, FMC South Rocky Mount was serving a total of 67 in-center patients. The facility was serving 42 in-center patients residing in Nash County and 16 in-center patients residing in Edgecombe County.
- The applicant projects growth of the Nash County patient population by using the Nash County Five Year AACR of 1.6%.
- Edgecombe County is contiguous to Nash County and currently 23.9% of the in-center patients at FMC South Rocky Mount are residents of Edgecombe County. The applicant projects growth of the Edgecombe County patient population using the Edgecombe County Five Year AACR of 5.5%.
- The applicant does not project growth of the Halifax and Wilson Counties patient census, but these patients will be added to projections of future patient populations at appropriate points in time.

¹ Analyst calculations are in brackets.

Projected utilization is reasonable and adequately supported because it is based on the recent historical experience at the facility.

Access to Medically Underserved Groups

In Section D, pages 41-42, the applicant states that the proposed relocation of the home therapy program and two existing dialysis station from FMC South Rocky Mount to Nash County Home will not have an effect on the ability of medically underserved groups to have convenient access to dialysis care because the Nash County Home will be located less than 10 miles from the existing FMC South Rocky Mount facility.

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

- The applicant provides a statement of its intent to continue serving medically underserved populations.
- The applicant's related facilities have a history of providing services to low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.

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.

The applicant proposes to relocate no more than two dialysis stations and the entire home therapy program from FMC South Rocky Mount to a new dialysis facility dedicated to home hemodialysis (HHD) and peritoneal dialysis (PD) training and support services.

In Section E.2, page 48, the applicant describes the alternative it considered and explains why the alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternative considered was:

- *Maintain the Status Quo* – The applicant states that maintaining the status quo is not an effective alternative because not relocating home therapies to a new location would not allow for expansion of home therapy services in Nash County. The applicant states that the growth of home therapy patient population is expected to continue as a result of the emphasis on home therapy by Boice-Willis Clinic nephrologists and home therapy initiatives that give in-center patients an opportunity to experience home dialysis and its benefits prior to converting to home dialysis.

On page 48, the applicant states that its proposal is the most effective alternative because a new location will allow for expansion of home therapy services in Nash County as home dialysis patient population continues to grow.

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

1. **FMS Boice-Willis Home, LLC (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
2. **The certificate holder shall establish a freestanding dialysis facility dedicated to home hemodialysis and peritoneal dialysis training and support to be known as Nash County Home by relocating no more than two stations from FMC South Rocky Mount.**

3. **Upon completion of this project, the certificate holder shall take the necessary steps to decertify two dialysis stations at FMC South Rocky Mount for a total of no more than 17 dialysis stations at FMC South Rocky Mount upon completion of the project.**
 4. **The certificate holder shall install plumbing and electrical wiring through the walls for no more than two dialysis 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 2, 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 relocate no more than two dialysis stations and the entire home therapy program from FMC South Rocky Mount to a new dialysis facility dedicated to home hemodialysis (HHD) and peritoneal dialysis (PD) training and support services.

Capital and Working Capital Costs

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

Capital Costs	
Construction/Renovation Contract(s)	\$1,032,094
Architect / Engineering Fees	\$92,472
Non-Medical Equipment	\$40,350
Furniture	\$103,592
Other: Contingency	\$51,374
Total	1,319,882

In Section Q, 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's construction cost was developed by the Fresenius Real Estate and Construction Services (RECS) team based upon a national database used by the RECS team.
- Architect and Engineering Fees are estimated at 9% of the proposed construction project.
- The Contingency amount is calculated as 4.5% of the sum of Construction and Architect / Engineering Fees.
- The Non-Medical Equipment is primarily comprised of any system necessary for dialysis operation.
- The Furniture estimate includes all necessary furniture for operation of the facility.

In Section F, pages 52-53, the applicant projects that start-up costs will be \$275,245 and initial operating expenses will be \$1,374,059 for a total working capital of \$1,649,304. On pages 52-53, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the following:

- The applicant states that it expects it could be as much as six months before the cash in-flow exceeds cash out-flow.
- The applicant's estimated start-up expenses is comprised of four weeks clinical supply/medications and staff salaries.
- The applicant calculates initial operating expenses as six months of the first-year expenses.

Availability of Funds

In Section F, pages 50 and 54, the applicant states that the capital cost will be funded by Fresenius Medical Care Holdings, Inc. as shown in the table below.

Sources of Capital Cost Financing

Type	FMS Boice-Willis Home, LLC
Loans	\$0
Accumulated reserves or OE*	\$1,319,882
Bonds	\$0
Other (Describe)	\$0
Total Financing	\$1,319,882

*OE = Owner's Equity

Sources of Working Capital Financing

Type	FMS Boice-Willis Home, LLC
Loans	\$0
Accumulated reserves or OE*	\$1,649,304
Bonds	\$0
Other (Describe)	\$0
Total Financing	\$1,649,304

*OE = Owner's Equity

The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project based on the following:

- Exhibit F-2 contains a letter dated September 16, 2024, from the Vice President of Corporate Tax – North America for Fresenius Medical Care Holdings, Inc. authorizing the use of accumulated reserves for the capital and working capital needs of the project.
- The applicant documents that it has adequate cash and assets to fund the capital and working capital costs of the project.

Financial Feasibility

The applicant provides pro forma financial statements for the first two full fiscal years of operation following completion of this project. In Section Q, Forms F.2 and F.4, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as summarized in the table below.

	1st Full Fiscal Year CY2027	2nd Full Fiscal Year CY2028
Total # of Treatments	7,733	7,929
Total Gross Revenue	\$48,648,700	\$49,878,328
Total Net Revenue	\$3,549,971	\$3,639,837
Average Net Revenue per Treatment	\$459	\$459
Total Operating Expenses	\$2,803,604	\$2,860,842
Average Operating Expense per Treatment	\$363	\$361
Net Income	\$746,367	\$778,995

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

- The applicant states that the gross revenue per treatment (base rate for dialysis services) is \$6,291.
- The applicant expenses are based upon the cost per treatment at the nearby FMC Hickory.
- Salary expenses are projected to increase at a rate of 2.0% annually.

- 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.
 - The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal.
 - 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 costs and charges.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to develop a new dialysis facility dedicated to home hemodialysis (HHD) and peritoneal dialysis (PD) training and support services by relocating no more than two dialysis stations and the entire home therapy program from FMC South Rocky Mount.

On page 113, the 2024 SMFP defines the service area for dialysis stations as, “... *the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” Both Nash County Home and FMC South Rocky Mount are located in Nash County. Thus, the service area for this application is Nash County. Facilities may serve residents of counties not included in their service area.

According to Table 9A on page 126 of the 2024 SMFP, there are four existing or approved dialysis facilities in Nash County. Fresenius Medical Care operates three of the four facilities in Nash County. Information on these dialysis facilities, from Table 9A of the 2024 SMFP, is provided below.

Nash County Dialysis Facilities			
Dialysis Facility	# of Certified Stations as of 12/31/2022	# of In-Center Patients as of 12/31/2022	Utilization Rate as of 12/31/2022
FMC of Spring Hope	16	45	70.31%
FMC South Rocky Mount	19	67	88.16%
Nash County Dialysis	12	25	52.08%
Rocky Mount Kidney Center	40	155	96.88%

In Section G, page 58, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Nash 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 Nash County that will continue to be used and exclusively dedicated to home hemodialysis training and support services. These stations have been previously approved and home therapy training and support services is already being offered. The applicant is merely proposing to relocate existing certified stations and existing home therapy services to a new location within the same county, less than 10-miles from where services are currently being offered, thus the proposed project will not duplicate any existing or approved services in Nash County.”

The applicant adequately demonstrates that the proposal will not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- The proposal would not result in a surplus of stations or increase an existing surplus of stations in Nash County.
- The applicant adequately demonstrates that the proposed relocation of the two stations for the development of a new facility dedicated exclusively to the training and support of home dialysis patients is needed in addition to the operational facilities in Nash 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 the reasons stated 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 relocate no more than two dialysis stations and the entire home therapy program from FMC South Rocky Mount to a new dialysis facility dedicated to home hemodialysis (HHD) and peritoneal dialysis (PD) training and support services.

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

Position	Projected FTE Staff	Projected FTE Staff
	1st Full Fiscal Year FY2027	2nd Full Fiscal Year FY2028
Administrator (FMC Clinic Manager)	1.00	1.00
Home Training Nurses (RNs)	5.00	5.00
Technicians (PCT)	2.00	2.00
Dietician	0.33	0.33
Social Worker	0.33	0.33
Maintenance	0.25	0.25
Administration/Business Office	0.50	0.50
Other (FMC Director of Operations)	0.25	0.25
Other (FMC Chief Technician)	0.15	0.15
Other (FMC In-Service)	0.15	0.15
TOTAL	9.96	9.96

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in the pro forma financials found in Section Q. In Section H, pages 60-61, 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 reasonably accounts for the FTE staffing positions necessary to accommodate the proposed healthcare services at Nash County Home.
- The costs are accounted for in the budgeted Operating Costs.
- The applicant describes the methods used to recruit or fill new positions and the existing training and continuing education programs that are provided.

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.

- (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 relocate no more than two dialysis stations and the entire home therapy program from FMC South Rocky Mount to a new dialysis facility dedicated to home hemodialysis (HHD) and peritoneal dialysis (PD) training and support services.

Ancillary and Support Services

In Section I, page 62, the applicant identifies each ancillary and support service listed in the application as necessary for the proposed services. On pages 62-67, the applicant explains how each ancillary and support service is made available.

The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant currently provides dialysis services at an existing facility in Nash County.
- The applicant discusses how it will provide each necessary ancillary and support service at Nash County Home.

Coordination

In Section I, page 67, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I-2.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant discusses its relationships with local health care providers.
- The applicant discusses its relationships with local social service providers.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

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

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

NA

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

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

C

The applicant proposes to relocate no more than two dialysis stations and the entire home therapy program from FMC South Rocky Mount to a new dialysis facility dedicated to home hemodialysis (HHD) and peritoneal dialysis (PD) training and support services.

In Section K, page 71, the applicant states that the project involves renovating 3,534 square feet of existing space. Line drawings are provided in Exhibit K-2.

On pages 73-74, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site. Supporting documentation is provided in Exhibit K-4. The site appears to be suitable for the proposed home dialysis training facility based on the applicant's representations and supporting documentation.

On pages 71-72, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative because the applicant states that finding an existing space for renovation is more cost effective than building new construction and the Fresenius Medical Care Real Estate and Construction Services team uses a national database to ensure the project costs are reasonable and accurate.

On page 72, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services because the applicant states that relocating two dialysis stations and the entire home therapy program will ensure convenient access to care for patients in the Nash County area and the costs of the relocation will be borne by the applicant and not passed on to the patient.

On pages 72-73, 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

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, that energy saving features have been incorporated into the construction plans, and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion.

- (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

The applicant proposes to relocate no more than two dialysis stations and the entire home therapy program from FMC South Rocky Mount to a new dialysis facility dedicated to home hemodialysis (HHD) and peritoneal dialysis (PD) training and support services.

Nash County Home will be a new facility and therefore has no history. In Section L.1, page 76, the applicant provides the historical payor mix during CY2023 for FMC South Rocky Mount, as shown in the table below.

Payor Category	FMC South Rocky Mount Historical Payor Mix CY2023					
	In-Center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	# of Total	# of Patients	% of Total	# of Patients	% of Total
Self-Pay	0.1	0.15%	0.0	0.00%	0.0	0.00%
Insurance	3.8	5.63%	2.7	30.54%	10.1	25.98%
Medicare*	57.1	85.20%	6.1	67.31%	27.3	69.91%
Medicaid*	4.1	6.16%	0.2	2.15%	1.2	3.10%
Misc. including VA	1.9	2.86%	0.0	0.00%	0.4	1.00%
Total	67.0	100.00%	9.0	100.00%	39.0	100.00%

Source: Section L, page 76.
 * Including any managed care plans.

In section L, page 77, the applicant provides the following comparison.

	Percentage of Total Patients Served [^]	Percentage of Population of the Service Area *
Female	45.7%	51.9%
Male	54.3%	48.1%
Unknown	0.0%	0.0%
64 and Younger	55.8%	80.2%
65 and Older	44.2%	19.8%
American Indian	0.0%	1.2%
Asian	0.8%	1.2%
Black or African American	72.9%	42.1%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	25.6%	53.4%
Other Race	0.8%	10.4%
Declined/Unavailable	0.0%	0.0%

Source: Section L, page 77.

^All patients (in-center, home hemodialysis, and peritoneal dialysis)

*The percentages can be found online using the United States Census Bureau's QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>. Just enter in the name of the 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 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 78, the applicant states that the facility is not obligated to provide uncompensated care, community service, or access by minorities and persons with disabilities.

The facility is not an operational facility; therefore, there have been no civil rights access complaints filed against the facility within the last five years.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 78, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as summarized in the following table.

Payor Category	Nash County Home Projected Payor Mix 2nd Full Fiscal Year CY2028					
	In-Center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	# of Total	# of Patients	% of Total	# of Patients	% of Total
Self-Pay	0.0	0.0%	0.0	0.00%	0.0	0.00%
Insurance	0.0	0.0%	3.2	30.54%	11.4	25.98%
Medicare*	0.0	0.0%	7.0	67.31%	30.6	69.91%
Medicaid*	0.0	0.00%	0.2	2.15%	1.4	3.10%
Misc. including VA	0.0	0.00%	0.0	0.00%	0.4	1.00%
Total	0.0	0.00%	10.4	100.00%	43.8	100.00%

Source: Section L, page 78.

* Including any managed care plans.

As shown in the table above, during the second full fiscal year of operation, the applicant projects 67.31% of HHD and 69.91% of PD services will be provided to Medicare patients, and 2.15% of HHD and 3.10% of PD services will be provided to Medicaid patients.

On page 79, the applicant provides the assumptions and methodology used to project payor mix during the second fiscal full years of operation following completion of the project. The projected payor mix is reasonable and adequately supported because the projected payor mix is based on the recent performance of FMC South Rocky Mount. The applicant is projecting that all the existing home therapy patients currently receiving monthly follow-up by the home therapy program at FMC South Rocky Mount will transfer to the proposed facility, Nash County Home, upon certification.

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.

In Section L, page 80, 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 relocate no more than two dialysis stations and the entire home therapy program from FMC South Rocky Mount to a new dialysis facility dedicated to home hemodialysis (HHD) and peritoneal dialysis (PD) training and support services.

In Section M, page 82, 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 applicant's statement that it has communicated with the local student nursing programs and provided a copy of a letter to Nash Community College encouraging the school to include the dialysis facility in their clinical rotations for nursing students.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

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

C

The applicant proposes to relocate no more than two dialysis stations and the entire home therapy program from FMC South Rocky Mount to a new dialysis facility dedicated to home hemodialysis (HHD) and peritoneal dialysis (PD) training and support services.

On page 113, the 2024 SMFP defines the service area for dialysis stations as, “... the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.” Both Nash County Home and FMC South Rocky Mount are located in Nash County. Thus, the service area for this application is Nash County. Facilities may serve residents of counties not included in their service area.

According to Table 9A on page 126 of the 2024 SMFP, there are four existing or approved dialysis facilities in Nash County. Fresenius Medical Care operates three of the four facilities in Nash County. Information on these dialysis facilities, from Table 9A of the 2024 SMFP, is provided below.

Nash County Dialysis Facilities			
Dialysis Facility	# of Certified Stations as of 12/31/2022	# of In-Center Patients as of 12/31/2022	Utilization Rate as of 12/31/2022
FMC of Spring Hope	16	45	70.31%
FMC South Rocky Mount	19	67	88.16%
Nash County Dialysis	12	25	52.08%
Rocky Mount Kidney Center	40	155	96.88%

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 83, the applicant states:

“The applicant does not expect this proposal to have any effect on the competitive climate in Nash County. The applicant does not project to serve dialysis patients currently being served by another provider.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 84, the applicant states:

“At the time this application was prepared and submitted, BMA was the only dialysis provider in Nash County offering in-center and home dialysis services. Approval of this application will allow for emphasis and future expansion of home therapy services in Nash County. This is an immediate and significantly positive impact to the patients of the area.”

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

Regarding the impact of the proposal on quality, in Section N, page 84, 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 C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 84, 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 C, D and L of the application and any exhibits.

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

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

Conclusion

The Agency reviewed the:

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

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

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

C

In Section Q Form O Facilities, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity.

In Section O.5, page 89, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care that resulted in a finding of “*Immediate Jeopardy*” 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 Fresenius Medical Care 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.

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.

10 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 establish 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 does not propose 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- The applicant is proposing to develop a new dialysis facility dedicated to home hemodialysis and peritoneal dialysis training and support services by relocating two existing dialysis stations and the entire home therapy program from FMC South Rocky Mount. In Section C, page 33, the applicant is projected to have 14.5 home hemodialysis patients utilizing two certified stations for an average of 7.25 home hemodialysis training patients per station by the end of first full fiscal year of operation. The applicant's projections meet the requirement of six home hemodialysis training patients per station.

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

-NA- The applicant does not propose to increase the number of home hemodialysis stations 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, pages, 28-29, and in the Assumptions following Form C in Section Q, pages 96-97, the applicant provides the assumptions and methodology used to project utilization. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.