

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: March 22, 2023

Findings Date: March 22, 2023

Project Analyst: Donna Donihi

Co-Signer: Mike McKillip

Project ID #: Q-12310-23

Facility: Beaufort County Home

FID #: 230038

County: Beaufort

Applicant: FMS ENA Home, LLC

Project: Develop a new dialysis facility dedicated to home hemodialysis and peritoneal dialysis training and support by relocating two dialysis stations and the entire home training program from FMC Pamlico

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 ENA Home, LLC (hereinafter “Beaufort County Home” or “the applicant”) proposes to develop a new dialysis facility dedicated to home hemodialysis (HH) and peritoneal dialysis (PD) training and support by relocating two dialysis stations and the entire home training program from FMC Pamlico.

The applicant does not propose to develop any beds or services for which there is a need determination or offer a new institutional health service for which there are any policies in the 2023 State Medical Facilities Plan. 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- (2) Repealed effective July 1, 1987.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 (HH) and peritoneal dialysis (PD) training and support by relocating two dialysis stations and the entire home training program from FMC Pamlico.

Patient Origin

On page 113, the 2023 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 Beaufort County Home and FMC Pamlico Dialysis Center are located in Beaufort County. Thus, the service area for this application is Beaufort County. Facilities may serve residents of counties not included in their service area.

This proposal is to develop Beaufort County Home, a new two-station home therapies dialysis facility in Beaufort County; therefore, historical patient data does not exist. In Section C, pages 23 and 26, the applicant provides the historical (CY2022) patient origin for FMC Pamlico, as summarized in the following tables.

FMC Pamlico 01/01/2022 -12/31/2022						
	In-Center		Home Hemodialysis		Peritoneal Dialysis	
County	IC Patients	% of Total	HH Patients	% of Total	PD Patients	% of Total
Beaufort	87	90.6%	7	53.8%	15	57.7%
Carteret					1	3.8%
Chowan			1	7.7%		
Craven	2	2.1%			3	11.5%
Hyde	3	3.1%	2	15.47%	1	3.8%
Martin					4	15.4%
Pasquotank			1	7.7%		
Pitt	3	3.1%	1	7.7%	1	3.8%
Washington	1	1.0%	1	7.7%	1	3.8%
Total	96	100.0%	13	100.0%	26	100.0%

Source: Section C page 23

In Section C.3, page 24, the applicant provides the projected, home hemodialysis (HH), and peritoneal dialysis (PD) patient origin for Beaufort County Home for the second full operating year following project completion (CY2026), as summarized in the following table.

Beaufort County Home 01/01/2026 -12/31/2026				
	Home Hemodialysis		Peritoneal Dialysis	
County	HH Patients	% of Total	PD Patients	% of Total
Beaufort	8.3	58.2%	17.9	57.7%
Carteret			1.0	3.8%
Chowan	1.0	7.0%		
Craven			3.0	11.5%
Hyde	2.0	13.9%	1.0	3.8%
Martin			4.0	15.4%
Pasquotank	1.0	7.0%		
Pitt	1.0	7.0%	1.0	3.8%
Washington	1.0	7.0%	1.0	3.8%
Total	14.3	100.0%	28.9	100.0%

Source: Section C, page 24.

In Section C.3, pages 24-29, the applicant provides the assumptions and methodology used to project Beaufort County Home’s patient origin. The applicant’s assumptions are reasonable and adequately supported because the projected patient origin is based the historical (CY2022) patient origin for home therapy patients in the FMC Pamlico home therapy program.

Analysis of Need

In Section C.4, pages 30-32, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

- Physicians are referring more patients to home dialysis and more patients are choosing to dialyze at home providing greater flexibility and increased time for other activities.
- Developments in the technology to perform remote monitoring has improved clinical outcomes and provided savings in travel time and expense.
- The FMC Pamlico facility does not allow for expansion.
- The statewide home patient population has grown at a higher rate than the overall ESRD patient population.
- The time to train one patient for HH and PD dialysis takes 6 hours per patient 4 times a week for 6 weeks totaling 25 training treatments prior to discharge limiting how many patients can be trained.
- The applicant does not have space at FMC Pamlico to expand to meet the need.

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

- There was an increase in the number and percentage of patients utilizing both types of home dialysis modalities between December 31, 2019 and December 31, 2022.
- The applicant provides a 2019 Executive Order in Exhibit C.4 proclaiming support for in home dialysis.

Projected Utilization

In Section C.3, pages 29-30 and Section Q, pages 88-99 the applicant provides the calculations used to project the Beaufort County patient utilization at the proposed Beaufort County Home facility, as illustrated in the following table.

	HHD Projections	PD Projections
The applicant begins with the Beaufort County home patient population dialyzing at FMC Pamlico on December 31, 2022	7	15
Project the Beaufort County patient population forward to December 31, 2023, using a 4.5% growth rate based on home therapy growth trends as discussed above.	$7 \times 1.045 = 7.3$	$15 \times 1.045 = 15.7$
Adds the 6 HHD patients and 11 PD patients from other counties. This is the projected ending census for the Interim Year 1.	$7.3 + 6 = 13.1$	$15.7 + 11 = 26.7$
Project the Beaufort County patient population forward to December 31, 2023, using a 4.5% growth rate based on the home therapy growth trends discussed above.	$7.3 \times 1.045 = 7.6$	$15.7 \times 1.045 = 16.4$
Adds the 6 HHD patients and 11 PD patients from other counties. This is the projected ending census for Interim Year 2.	$7.6 + 6 = 13.6$	$16.4 + 11 = 27.4$
Project the Beaufort County patient population forward to December 31, 2025, using a 4.5% growth rate based on the home therapy growth trends discussed above.	$7.6 \times 1.045 = 8.0$	$16.4 \times 1.045 = 17.1$
Adds the 6 HHD patients and 11 PD patients from other counties. This is the projected ending census for the Operating Year 1 .	$8.0 + 6 = 14$	$17.1 + 11 = 28.1$
Project the Beaufort County patient population forward to December 31, 2026, using a 4.5% growth rate based on the home therapy growth trends discussed above.	$8.0 \times 1.045 = 8.3$	$17.1 \times 1.045 = 17.9$
Adds the 6 HHD patients and 11 PD patients from other counties. This is the projected ending census for Operating Year 2 .	$8.3 + 6 = 14.3$	$17.9 + 11 = 28.9$

In Section C pages 24-30 and Section Q, Form C. page 88, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The applicant begins with the HH and PD patient population served at FMC Pamlico as of December 31, 2022.
- The applicant applies an annual growth rate of 4.5% based on the Beaufort County home therapy growth and FMC Pamlico home therapy patient growth from 2019 to 2023.

- The applicant does not project any growth in the patients residing outside of Beaufort County.

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

- The applicant begins projections with the existing Beaufort County patients receiving home dialysis training and support at FMC Pamlico in Beaufort County.
- The applicant provides documentation regarding the historical growth in home therapy patients at FMC facilities in general and FMC Pamlico, specifically.

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	39.5%
Racial and ethnic minorities	39.5%
Women	23.7%
Persons with disabilities	5.3%
Persons 65 and older	23.7%
Medicare beneficiaries	34.2%
Medicaid recipients	39.5%

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 historical experience at FMC Pamlico.

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 the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.

- The applicant describes the extent to which all residents, including underserved groups, are likely to have access to the proposed services and adequately supports its assumptions.
- (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 HH and PD training and support by relocating two existing stations from FMC Pamlico. FMC Pamlico will be certified for 29 stations upon completion of this project.

In Section D, pages 42-44, the applicant explains why it believes the needs of the population presently utilizing the services to be relocated will be adequately met following completion of the project.

On page 39, the applicant provides a table which shows projected FMC Pamlico utilization following the relocation of two stations to the proposed facility, Beaufort County Home.

FMC Pamlico		
	In-Center Stations	In-Center Patients
The applicant begins with the Beaufort County patients dialyzing at FMC Pamlico as of December 31, 2022.	31	87
The applicant projects the patient population forward one year to December 31, 2023 using a 4.5% growth rate based on the facility's historical growth.		$87 \times 1.045 = 90.9$
The applicant adds 9 in-center patients from other counties for the projected ending census for Interim Year 1.		$90.9 + 9 = 99.9$
The applicant projects the patient population forward one year to December 31, 2024 using a 4.5% growth rate based on the facility's historical growth.		$90.9 \times 1.045 = 95.0$
The applicant adds 9 in-center patients from other counties for the projected ending census for Interim Year 2.		$95 + 9 = 104$
Beaufort County Home is projected to be certified on 1/1/2025. Two existing stations are projected to be relocated from FMC Pamlico.	$31 - 2 = 29$	104
The applicant projects the patient population forward one year to December 31, 2025 using a 4.5% growth rate based on the facility's historical growth.		$95 \times 1.045 = 99.3$
The applicant adds 9 in-center patients from other counties for the projected ending census for Operating Year 1.		$99.3 + 9 = 108.3$
The applicant projects the patient population forward one year to December 31, 2026 using a 4.5% growth rate based on the facility's historical growth.		$99.3 \times 1.045 = 103.7$
The applicant adds 9 in-center patients from other counties for the projected ending census for Operating Year 2.		$103.7 + 9 = 112.7$

As shown in the table above, FMC Pamlico is projected to serve 104 in-center patients on 29 stations as of the date the stations are projected to be relocated. Thus, the applicant projects that FMC Pamlico will have a utilization rate of 89.66% or 3.59 patients per station per week ($104 \text{ patients} / 29 \text{ stations} = 3.59 / 4 = 0.8966$ or 89.66%).

On pages 42-43, the applicant states:

“The site for the new Beaufort County Home facility is less than five miles from the existing FMC Pamlico facility, according to Google Maps. BMA is projecting the existing home therapy patient currently receiving treatment at the FMC Pamlico facility relocate to the new Beaufort County Home facility upon project completion. Thus, all patients will continue to have convenient access to dialysis care.”

Access to Medically Underserved Groups

In Section D, page 41, the applicant states:

“The site for the new Beaufort County Home facility is less than five miles from the existing FMC Pamlico facility, according to Google Maps, thus the needs of patients who are currently utilizing these services will be adequately met following relocation of these services to the new freestanding home therapy facility location, including services to the [medically underserved] groups listed [on page 41 of the application].”

The applicant adequately demonstrates that the needs of medically underserved groups that will continue to use home dialysis training and support 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.

CA

The applicant proposes to develop a new dialysis facility dedicated to home hemodialysis (HH) and peritoneal dialysis (PD) training and support by relocating two dialysis stations and the entire home training program from FMC Pamlico.

In Section E.2, page 46, the applicant describes the alternatives considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the identified need. The alternatives considered were:

- *Maintain the Status Quo* - The applicant states that maintaining the status quo is not an effective alternative because of the projected growth in the home dialysis patient population. Therefore, the applicant determined this is not the most effective alternative.
- *Relocate a different number of existing stations to the proposed facility*- The applicant states that it could have propose the relocation of one or more than two stations, but that projected patient population dictates that two stations is the appropriate number.

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

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why they believe 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 ENA Home, LLC (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall develop a new kidney disease treatment center dedicated to home hemodialysis and peritoneal dialysis training and support to be known as Beaufort County Home by relocating no more than two in-center and home hemodialysis stations from FMC Pamlico.**
- 3. Upon completion of this project, the certificate holder shall take the necessary steps to decertify two stations at FMC Pamlico for a total of no more than 29 in-center and home hemodialysis stations upon completion of the project.**
- 4. 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, 2022. The second progress report shall be due on October 1, 2022 and so forth.
5. The certificate holder shall install plumbing and electrical wiring through the walls for no more than 2 in-center and home hemodialysis stations.
 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 (HH) and peritoneal dialysis (PD) training and support by relocating two dialysis stations and the entire home training program from FMC Pamlico.

Capital and Working Capital Costs

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

Construction Costs	\$1,101,470
Non-medical equipment	\$54,997
Furniture	\$85,483
Miscellaneous Costs	\$159,162
Total	\$1,401,112

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 uses the Fresenius’s Real Estate and Construction Services team to develop the capital cost for the project.
- The applicant relies on its corporate experience to project costs furniture, fixtures and equipment.

In Section F, page 49, the applicant states it projects \$201,249 in start-up costs and \$422,520 initial operating expenses, for total working capital required of \$623,769.

Availability of Funds

In Section F, pages 47 and 51, the applicant states that the capital and working capital cost, respectively, will be funded by FMS ENA Home, LLC, as shown in the tables below.

Sources of Capital Cost Financing

Type	FMS ENA Home, LLC
Loans	\$0
Accumulated reserves or OE *	\$1,401,112
Bonds	\$0
Other (Specify)	\$0
Total Financing	\$1,401,112

* OE = Owner’s Equity

Sources of Working Capital Financing

Type	FMS ENA Home, LLC
Loans	\$0
Accumulated reserves or OE *	\$623,769
Bonds	\$0
Other (Specify)	\$0
Total Financing	\$623,769

* OE = Owner’s Equity

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

- Exhibit F-2 contains a letter dated January 17, 2023 from the Senior Vice President and Treasurer 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.

Beaufort County Home Projected Revenue and Operating Expenses		
	1st Full Fiscal Year CY2025	2nd Full Fiscal Year CY2026
Treatments	5,763	6,372
Gross Patient Revenue	\$36,253,899	\$40,087,762
Net Patient Revenue	\$2,246,413	\$2,473,776
Average Net Revenue per Treatment	\$390	\$388
Total Operating Expenses	\$1,718,739	\$1,823,535
Average Operating Expense per Treatment	\$298	\$286
Net Income	\$527,674	\$650,241

Totals may not sum due to rounding

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 bases charges and expenses on historical revenue and expenses for the applicant's other North Carolina facilities.
- 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 (HH) and peritoneal dialysis (PD) training and support by relocating two dialysis stations and the entire home training program from FMC Pamlico.

On page 113, the 2023 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 Beaufort County Home and FMC Pamlico Dialysis Center are located in Beaufort County. Thus, the service area for this application is Beaufort County. Facilities may serve residents of counties not included in their service area.

According to Table 9A on page 129 of the 2022 SMFP, FMC Pamlico is the only existing dialysis facilities in Beaufort County. Information on this dialysis facility, from Table 9A of the 2022 SMFP, is summarized below.

Beaufort County Dialysis Facilities

Dialysis Facility	Certified Stations as of 12/31/2020	# of In-Center Patients as of 12/31/2020	Percent Utilization as of 12/31/2020
FMC Pamlico	31	91	73.39%

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

"The applicant is not proposing to develop new dialysis stations by this proposal. The applicant proposed to relocate existing certified dialysis stations within Beaufort County that will be exclusively to home hemodialysis services. These stations have been previously approved and do not duplicate any existing or approve services."

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 Beaufort 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 Beaufort County.

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 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 develop a new dialysis facility dedicated to home hemodialysis (HH) and peritoneal dialysis (PD) training and support by relocating two dialysis stations and the entire home training program from FMC Pamlico.

In Section Q, Form H, the applicant provides the projected staffing in full-time equivalent (FTE) positions for the first and second full operating years of the proposed services, as summarized in the following table.

Beaufort County Home

POSITION	PROJECTED FTE POSITIONS CY2025	PROJECTED FTE POSITIONS CY2026
Administrator	1.00	1.00
Home Training Nurse	2.00	2.00
Techicians	1.00	1.00
Dietitian	0.33	0.33
Social Worker	0.33	0.33
Maintenance	0.25	0.25
Admin/Business Office	0.25	0.25
Director of Operations	0.33	0.33
Chief Technician	0.15	0.15
In-Service	0.15	0.15
Total	5.79	5.79

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 57-58, 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 Beaufort County Home.
- The costs are accounted for in the budgeted Operating Costs.
- The methods used to recruit or fill new positions and the existing training and continuing education programs 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 develop a new dialysis facility dedicated to home hemodialysis (HH) and peritoneal dialysis (PD) training and support by relocating two dialysis stations and the entire home training program from FMC Pamlico.

Ancillary and Support Services

In Section I, page 59, the applicant identifies each ancillary and support service listed in the application as necessary for the proposed services. On pages 59-64, 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 Beaufort County.
- The applicant discusses how it will provide each necessary ancillary and support service at Beaufort County Home.

Coordination

In Section I, page 64, 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.

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

NA

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

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

C

The applicant proposes to develop a new dialysis facility dedicated to home hemodialysis (HH) and peritoneal dialysis (PD) training and support by relocating two dialysis stations and the entire home training program from FMC Pamlico.

In Section K, page 67, the applicant states that the project will involve construction of 4,269 square feet of space. The proposed floor plan is provided in Exhibit K.2.

On page 69, the applicant identifies the proposed site. The applicant 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 in Exhibit K-4. The site appears to be suitable for the proposed dialysis home training facility based on the applicant's representations and supporting documentation.

On pages 67-68, the applicant adequately explains how the cost, design and means of construction represent a reasonable alternative for the proposal based on the fact that the site is close to the existing FMC Pamlico facility and convenient to patients. :

On page 68, 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 developing the new facility will be borne by the applicant and not be passed along to the public.

On pages 68-69, the applicant identifies applicable energy saving features that will be incorporated into the construction plans.

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 develop a new dialysis facility dedicated to home hemodialysis (HH) and peritoneal dialysis (PD) training and support by relocating two dialysis stations and the entire home training program from FMC Pamlico.

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Beaufort County Home will be a new facility and therefore has no history. In Section L.1, page 73, the applicant provides the historical payor mix for CY2021 for FMC Pamlico, as shown in the table below.

FMC Pamlico Historical Payor Mix (CY2021)						
Payor Source	IC		HH		PD	
	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients
Self-Pay	1.4	1.7%	0.0	0.0%	0.0	0.0%
Insurance*	3.1	3.5%	0.0	0.0%	6.1	17.9%
Medicare*	73.6	84.5%	16.0	100.0%	24.7	72.7%
Medicaid*	7.3	8.4%	0.0	0.0%	0.8	2.3%
Misc. (including VA)	1.6	1.9%	0.0	0.0%	2.4	7.2%
Total	88.0	100.0%	0.0	100.0%	34.0	100.0%

*Including any managed care plans

Note: Table may not foot due to rounding

In section L, page 74, the applicant provides the following comparison.

	Percentage of Total FMC Pamlico Patients Served during the Last Full OY	Percentage of the Population of the Service Area Where the Stations are Located*
Female	23.7%	52.0%
Male	76.3%	48.0%
Unknown	0.0%	0.0%
64 and Younger	76.3%	75.0%
65 and Older	23.7%	25.0%
American Indian	0.0%	1.2%
Asian	0.0%	0.6%
Black or African-American	57.9%	24.2%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	39.5%	72.1%
Other Race	0.0%	10.3%
Declined / Unavailable	0.0%	0.0%

*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 74, the applicant states that the facility is not obligated to provide uncompensated care or community service.

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 75, 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.

**Beaufort County Home
 Projected Payor Mix CY2026**

Payment Source	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%	0.00	0.0%	0.0	0.0%
Insurance*	0.0	0.0%	0.00	0.0%	5.2	17.9%
Medicare*	0.0	0.0%	14.3	100.0%	21.0	72.7%
Medicaid*	0.0	0.0%	0.00	0.0%	0.7	2.3%
Other (VA)	0.0	0.0%	0.00	0.0%	2.1	7.2%
Total	0.0	0.0%	14.3	100.0%	28.9	100.0%

Totals may not sum due to rounding
 *Including any managed care plans

As shown in the table above, during the second full calendar year of operation, the applicant projects 100% of HHD and 72.7% of PD services will be provided to Medicare patients, and 2.3% of PD services will be provided to Medicaid patients.

On page 75, 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 historical payor mix of HHD and PD patients in existing home program at FMC Pamlico.

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section L, page 77, 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.5.

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 (HH) and peritoneal dialysis (PD) training and support by relocating two dialysis stations and the entire home training program from FMC Pamlico.

In Section M, page 78, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-1. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the applicant's description of its efforts to reach out to training programs and the fact that the applicant provides a copy of the letter to Eastern Carolina University offering the facility as a training site for nursing students.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to develop a new dialysis facility dedicated to home hemodialysis (HH) and peritoneal dialysis (PD) training and support by relocating two dialysis stations and the entire home training program from FMC Pamlico.

On page 113, the 2023 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 Beaufort County Home and FMC Pamlico Dialysis Center are located in Beaufort County. Thus, the service area for this application is Beaufort County. Facilities may serve residents of counties not included in their service area.

According to Table 9A on page 129 of the 2022 SMFP, FMC Pamlico is the only existing dialysis facilities in Beaufort County. Information on this dialysis facility, from Table 9A of the 2022 SMFP, is summarized below.

Beaufort County Dialysis Facilities

Dialysis Facility	Certified Stations as of 12/31/2020	# of In-Center Patients as of 12/31/2020	Percent Utilization as of 12/31/2020
FMC Pamlico	31	91	73.39%

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 80, the applicant states, “*The applicant does not expect this proposal to have any affect on the competitive climate in Beaufort County.*”

Regarding the impact of the proposal on cost effectiveness, quality, and access to medically underserved groups in Section N, page 80, the applicant states:

“This is a proposal to relocate two dialysis stations and the entire home therapy program from FMC Pamlico to a new freestanding dialysis facility, Beaufort County Home, that will be exclusively dedicated to home hemodialysis (HHD) and peritoneal dialysis (PD) training and support services. ... At the time this application was prepared and submitted, FMC Pamlico was the only dialysis facility in Beaufort County offering in-center and home dialysis services. Approval of this application will allow for emphasis and future expansion of home therapy services in Beaufort County. This is an immediate and significantly positive impact to the patients of the area. ... Quality of care is always in the forefront at Fresenius Medical Care related facilities. Quality care is not negotiable. ... Fresenius Medical Care related facilities in North Carolina have a history of providing dialysis services to the underserved populations of 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.”

See also Sections B, C, F, L, N, O and Q 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 85, 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 the 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.

NA

The applicant proposes to develop a new kidney disease treatment center dedicated to providing home training and support services for home hemodialysis and peritoneal dialysis patients. The applicant does not propose to include any certified in-center stations as a part of the proposed project. The Criteria and Standards for End Stage Renal Disease Services, promulgated in 10A NCAC 14C .2200, are not applicable to this review due to a declaratory ruling issued by the Agency on October 10, 2018, which exempts the Criteria and Standards from applying to proposals to develop or expand facilities exclusively serving home hemodialysis and peritoneal dialysis patients.