

## **REQUIRED STATE AGENCY FINDINGS**

### **FINDINGS**

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: March 28, 2025

Findings Date: March 28, 2025

Project Analyst: Chalice L. Moore

Co-Signer: Gloria C. Hale

Project ID #: L-12583-25

Facility: Halifax County Home

FID #: 250048

County: Halifax

Applicant(s): FMS Boice Willis Home, LLC

Project: Develop a new dialysis facility dedicated to home hemodialysis and peritoneal dialysis training and support by relocating no more than 2 in-center dialysis stations and the entire home training program from BMA of Roanoke Rapids

## **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 (hereinafter referred to as “the applicant” or Halifax County Home) proposes to develop a new dialysis facility dedicated to home hemodialysis and peritoneal dialysis training and support by relocating no more than two in-center dialysis stations and the entire home training program from BMA of Roanoke Rapids to a freestanding dialysis facility, Halifax County Home, that will be exclusively dedicated to home dialysis and peritoneal dialysis upon project completion.

The applicant does not propose to develop any beds or services or acquire any medical equipment for which there is a need determination in the 2024 SMFP or offer a new institutional health service for which there are any applicable 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- (2) Repealed effective July 1, 1987.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 develop a new dialysis facility dedicated to home hemodialysis and peritoneal dialysis training and support by relocating no more than two in-center dialysis stations and the entire home training program from BMA of Roanoke Rapids.

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

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

<b>BMA of Roanoke Rapids Dialysis Historical Patient Origin</b>						
<b>Last Full FY</b>						
<b>CY 2024</b>						
County	# of IC Patients	% of Total	# of HH Patients	% of Total	# of PD Patients	% of Total
Halifax	108.0	73.5%	5.0	100.0%	18.0	85.7%
Brunswick	2.0	1.4%				
Nash					1.0	4.8%
Northampton	36.0	24.5%			2.0	9.5%
Pitt						
Warren	1.0	0.7%				
Virginia						
<b>Total</b>	<b>147.0</b>	<b>100.0%</b>	<b>5.0</b>	<b>100.0%</b>	<b>21.0</b>	<b>100.0%</b>

Source: Section C, page 23

The following table illustrates projected patient origin for the proposed Halifax County Home facility.

<b>BMA of Roanoke Rapids Patient Origin</b>						
<b>Second Full FY</b>						
<b>CY 2029</b>						
County	# of IC Patients	% of Total	# of HH Patients	% of Total	# of PD Patients	% of Total
Halifax			10.4	100.0%	24.2	85.8%
Nash					1.0	3.5%
Northampton					3.0	10.6%
<b>Total</b>			<b>10.4</b>	<b>100.0%</b>	<b>28.2</b>	<b>100.0%</b>

Source: Section C, page 23

In Section C, pages 23-24, the applicant provides the assumptions and methodology used to project patient origin. The applicant's assumptions are reasonable and adequately supported because the patients already dialyzing at home and reporting to BMA of Roanoke Rapids are expected to transfer their care to Halifax County Home and receive their monthly follow-up visit there going forward.

### **Analysis of Need**

In Section C, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On pages 24-28, the applicant states:

- The increase in the home dialysis population in North Carolina
- The presence of nephrologists at the Boice-Willis Clinic in adjacent Edgecombe County and their treatment of chronic kidney disease (CKD) and end-stage renal disease (ESRD) patients, including those from Halifax County
- Halifax County home therapy growth with the recent addition of privileges of the nephrologists at Boice-Willis Clinic to BMA of Roanoke Rapids
- Susceptibility of Halifax County's 65+ population to COVID-19 and other diseases which make those with chronic kidney disease good candidates for home therapy
- Growth of the BMA of Roanoke Rapids patient population, including a 22.2% increase in Halifax County home therapy patients from December 31, 2022 to December 31, 2023
- Expected Halifax County home penetration due to higher percentages of home therapy patients in neighboring Edgecombe and Nash counties

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

- The availability of nephrologists recently granted privileges should expand access to the proposed home therapies.
- The applicant adequately demonstrates need based on the facility's projected growth in the home therapy patient population.

### Projected Utilization

#### *Home Methodology:*

In Section C, pages 26, and in Form Utilization C Section Q, the applicant provides the home hemodialysis (HHD) and peritoneal dialysis (PD) projected utilization for Halifax County Home, which is summarized as follows:

- The applicant begins with the current home dialysis patient population at BMA of Roanoke Rapids, as of December 31, 2024. These patients are all existing HHD and PD patients who already dialyze at home and report to BMA of Roanoke Rapids for their monthly follow-up visit. This information will be reported on the 2024 ESRD Data Collection Form that will be submitted to DHSR Planning in February 2025 and will be available to the CON Project Analyst during this review.
- On December 31, 2022, BMA of Roanoke Rapids was serving a total of 22 home dialysis patients. As of December 31, 2023, BMA of Roanoke Rapids was serving a total of 28 home dialysis patients, an increase of 27.3%. As of December 31, 2024, BMA of Roanoke Rapids had a total of 26 home dialysis patients, 23 of which were residents of Halifax County. The applicant notes that the slight decline in the total number of home dialysis patients at BMA of Roanoke Rapids between December 31, 2023 and December 31, 2024, includes the number of patients who have either moved away, received a transplant or expired and is not to be interpreted as a lack of growth.
- The Halifax County 5-Year Average Annual Change Rate (AACR) in the 2025 State Medical Facilities Plan (SMFP) is 1.8%. However, the applicant will project growth of the Halifax County patient population using a 1.2% growth rate. This growth rate is based on a 2-Year Compound Annual Growth Rate (CAGR) for BMA of Roanoke Rapids Halifax County patients between December 31, 2023 (128 total patients) and December 31, 2024 (131 total patients).
- The applicant will project that two Halifax County in-center hemodialysis (ICHD) patients will convert to home therapy each year, one HHD and one PD. The applicant believes that this is reasonable given the emphasis on home therapy by BMA and the nephrologists of the Boice-Willis Clinic, growth of home therapy statewide, particularly in HHD, an increased presence and growth of ESRD patients by the nephrologists of The Boice-Willis Clinic and growth of BMA of Roanoke Rapids total patient population, total Halifax County patient population, total home therapy patient population and total Halifax County home therapy patient population.
- The facility also served a total of four home dialysis patients from Nash and Northampton counties. These counties are contiguous to Halifax County; thus, it is reasonable to conclude that patients residing in these counties would continue to receive their monthly follow-up at a dialysis facility in Halifax County as they already do and as a function of patient choice, especially given that these patients do not travel 3x a week to a clinic like in-center patients.

- The applicant will not project growth of the Nash and Northampton counties' patient population, but these patients will be added to projections of future patient populations at appropriate points in time.
- The stations being relocated from BMA Roanoke Rapids to the new Halifax County Home are existing stations that are already certified and that are projected to be certified at the new facility on December 31, 2027.
  - Operating Year 1 is the period from January – December 31, 2028
  - Operating Year 2 is the period from January – December 31, 2029

Halifax County Home	HHD	PD
Begin with the Halifax County Home dialysis patient population dialyzing at BMA of Roanoke Rapids on December 31, 2024.	5.0	18.0
Project the Halifax County patient population forward one year to December 31, 2025.	$5.0 \times 1.012 = 5.1$	$18.0 \times 1.012 = 18.2$
Convert two ICHD patients to home dialysis, one for each modality.	$5.1 + 1 = 6.1$	$18.2 + 1 = 19.2$
Add the patients from other counties. This is the projected ending census for Interim Year 1.		$19.2 + 4 = 23.2$
Project the Halifax County patient population forward one year to December 31, 2026.	$5.1 \times 1.012 = 6.1$	$18.2 \times 1.012 = 19.4$
Convert two ICHD patients to home dialysis, one for each modality.	$6.1 + 1 = 7.1$	$19.4 + 1 = 20.4$
Add the patients from other counties. This is the projected ending census for Interim Year 2.		$20.4 + 4.0 = 24.4$
Project the Halifax County patient population forward one year to December 31, 2027.	$6.1 \times 1.012 = 7.2$	$19.4 \times 1.012 = 20.7$
Convert two ICHD patients to home dialysis, one for each modality	$7.2 + 1 = 8.2$	$20.7 + 1 = 21.7$
Add the patients from other counties. This is the projected ending census for Interim Year 3.		$21.7 + 4.0 = 25.7$
Project the Halifax County patient population forward one year to December 31, 2028.	$7.2 \times 1.012 = 8.3$	$20.7 \times 1.012 = 22.0$
Convert two ICHD patients to home dialysis, one for each modality.	$8.3 + 1 = 9.3$	$22.0 + 1 = 23.0$
Add the patients from other counties. This is the projected ending census for Operating Year 1.		$23.0 + 4.0 = 27.0$
Project the Halifax County patient populations forward one year to December 31, 2029.	$8.3 \times 1.012 = 9.4$	$22.0 \times 1.012 = 23.2$
Convert two ICHD patients to home dialysis, one for each modality.	$9.4 + 1 = 10.4$	$23.2 + 1 = 24.2$
Add the patients from the other counties. This is the projected ending census for Operating Year 2.		$24.2 + 4.0 = 28.2$

Source: Section C, page 30

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

Halifax County	Operating Year 1	Operating Year 2
Home Hemodialysis	9.3	10.4
Peritoneal Dialysis	27.0	28.2

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

- The applicant accounts for PD patients in adjacent counties who currently receive services in Halifax County, adding them to the facility census at appropriate points in time.
- The applicant's projected utilization in the first two years of operation is based on a more conservative growth rate than the 5-Year AACR for Halifax County, reflective of historical facility growth.

### **Access to Medically Underserved Groups**

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

*"The applicant, and its parent organization, Fresenius Medical Care, has a long history of providing dialysis services to the underserved populations of North Carolina. The Form within Section Q identifies Fresenius Medical Care related dialysis facilities in North Carolina... Fresenius Medical Care operates more than 100 dialysis facilities across North Carolina. Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved groups. It is a corporate policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, or health insurer."*

Medically Underserved Groups	Estimated Percentage of Total Patients during the Second Full Fiscal Year
Low-income persons	38.9%
Racial and ethnic minorities	88.6%
Women	46.9%
Persons with Disabilities	44.6%
Persons 65 and older	48.6%
Medicare beneficiaries	80.0%
Medicaid recipients	38.9%

Source: Section C, page 36

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the applicant's history of providing services to medically underserved groups and its statement that these groups will continue to have access to its services.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

C

The applicant proposes to develop a new dialysis facility dedicated to home hemodialysis and peritoneal dialysis training and support by relocating no more than two in-center dialysis stations and the entire home training program from BMA of Roanoke Rapids.

In Section D, pages 41-42, the applicant explains why it believes the needs of the population presently utilizing the services to be relocated will be met following completion of the project.

The applicant states,

*“The distance between the existing BMA of Roanoke Rapids facility where home therapy services are currently being offered and the location of the proposed freestanding home therapy facility is less than five miles according to Google Maps, thus the needs of the patients who are currently utilizing these services will be adequately met following the relocation of these services to the new freestanding home therapy facility location, including services to the groups listed above.”*

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

- All of the home therapy patients will transfer their care to Halifax County Home which is approximately five miles away from BMA of Roanoke Rapids.
- The applicant reasonably projects that the in-center patients continuing to dialyze at BMA of Roanoke Rapids will have adequate access since the facility is projected to have a utilization rate of 77.5% at the end of the third operating year after completion of the proposed project.

On page 42, the applicant provides a table of the stations that will be reduced from BMA of Roanoke Rapids and relocated to Halifax County Home in the table below:



<b>BMA of Roanoke Rapids</b>	
Halifax County where the facility is located	Halifax
1. Total number of existing, approved, and proposed dialysis stations as of the application deadline	50
2. Number of existing dialysis stations to be reduced, relocated or eliminated in the proposal	2
3. Total number of dialysis stations upon completion of this project and all other projects involving this facility	48

Source: Section D, page 42

In Section D, page 43, the applicant provides a table showing the utilization of BMA of Roanoke Rapids as of December 31, 2024 as summarized below:

<b>BMA of Roanoke Rapids</b>			
	ICHD	HHD	PD
Halifax	108.0	5.0	18.0
Brunswick	2.0		
Nash			1.0
Northampton	36.0		2.0
Pitt			
Warren	1.0		
<b>Total</b>	<b>147.0</b>	<b>5.0</b>	<b>21.0</b>

In Section D, pages 43-44, the applicant provides its methodology and assumptions for projecting utilization for BMA of Roanoke Rapids following relocation of two stations to Halifax County Home as follows:

1. The applicant begins projections of the future patient population to be served with the facility census as of December 31, 2024.
2. The applicant states the Halifax County 5-Year Average Annual Change Rate (AACR) in the 2025 SMFP is -1.8%. However, the applicant projects growth of the Halifax County patient population using a 1.2% growth rate based on a two-year growth rate from December 31, 2022 and December 31, 2024.
3. The facility was serving a total of 39 in-center patients residing in Brunswick, Northampton, and Warren County. Warren County is contiguous to Halifax County. It is reasonable to expect that patients residing in this county will continue at BMA of Roanoke Rapids.
4. The applicant states that Northampton County is also contiguous with Halifax County. Currently, 24.2% of in-center patients at BMA of Roanoke Rapids are residents of Northampton County. It is reasonable to conclude that patients residing in this county will continue to receive dialysis at BMA of Roanoke Rapids as a function of patient choice.
5. The applicant states that the Northampton County 5-Year AACR in the 2025 SMFP

is -.07%. However, the applicant projects growth of the Northampton County patient population at BMA of Roanoke Rapids using a 4.4% growth rate based on two-year growth rate from December 31, 2022 and December 31, 2024.

6. The stations being relocated from BMA of Roanoke Rapids are projected to be certified at the new Halifax County Home facility on December 31, 2027.

Operating Year 1 is the period from January 1- December 31, 2028

Operating Year 2 is the period from January 1- December 31, 2029

Halifax County Home	HHD
Begin with the Halifax County population as of December 31, 2024.	108.0
Project the Halifax County patient population forward one year to December 31, 2025.	$108.0 \times 1.012 = 109.3$
Subtract the two ICHD patients expected to convert to home dialysis.	$109.3 - 2 = 107.3$
Begin with the Northampton County patient population as December 31, 2024.	36.0
Project the Northampton County patient population forward as of December 31, 2025.	$36 \times 1.044 = 37.6$
Add the one in-center patient from Warren County. This is the projected ending census for Interim Year 1.	$107.3 + 37.6 + 1.0 = 145.9$
Project the Halifax County patient population forward one year to December 31, 2026.	$107.3 \times 1.012 = 108.6$
Subtract the two ICH patients expected to convert to home dialysis.	$108.6 - 2 = 106.6$
Project the Northampton County patient population forward one year to December 31, 2026.	$37.6 \times 1.044 = 39.2$
Add the one in-center patient from Warren County. This is the projected ending census for Interim Year 2.	$106.6 + 39.2 + 1.0 = 146.8$
Project the Halifax County patient population forward one year to December 31, 2027.	$106.6 \times 1.012 = 107.9$
Subtract the two ICHD patients expect to convert to home dialysis.	$107.9 - 2 = 105.9$
Project the Northampton County patient population forward one year to December 31, 2027.	$39.2 \times 1.044 = 41.0$
Add the one in-center patient from Warren County. This is the projected ending census for Interim Year 3.	$105.9 + 41.0 + 1.0 = 147.9$

The applicant states BMA of Roanoke Rapids is projected to have an in-center census of 147.9 patients as of December 31, 2027. The utilization is calculated as the following:

147.9 patients dialyzing on 48 stations  $(147.9/48) = 3.10$  patients per station per week  
or a utilization rate of 77.5%.

### **Access to Medically Underserved Groups**

In Section D, page 44, the applicant states the proposed relocation of two stations will not have any effect on the ability of medically underserved groups to access dialysis care because BMA of Roanoke Rapids will have a sufficient capacity for ICHD patients. In addition, in Section C, page 41, the applicant states that these groups will continue to have access to services.

The applicant adequately demonstrates the needs of medically underserved groups will be adequately met following completion of the project based on BMA of Roanoke Rapids history of providing care to these groups and its statements assuring continued access.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

### **C**

The applicant proposes to develop a new dialysis facility dedicated to home hemodialysis and peritoneal dialysis training and support by relocating no more than two in-center dialysis stations and the entire home training program from BMA of Roanoke Rapids.

In Section E, page 49, the applicant states there were no alternatives considered and explains why there were no alternatives available.

The applicant states,

*“Halifax County Home believes that the emphasis on expanding dialysis therapies will result in more patient choosing home dialysis. Halifax County Home seeks to be the provider of choice for home dialysis training and support services in Halifax and surrounding counties, resulting in improved quality of life, quality of care and patient outcomes by offering a more convenient alternative for dialysis treatment over the traditional in-center model of traveling to an in-center clinic 3x a week”.*

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

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

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 1. FMS Boice Willis Home, LLC, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall relocate no more than two in-center dialysis stations and the entire home training program from BMA of Roanoke Rapids to establish a freestanding dialysis facility dedicated to home hemodialysis and peritoneal dialysis training and support to be known as Halifax County Home.**
- 3. Upon the completion of this project, the certificate holder shall take the necessary steps to decertify two in-center dialysis stations at BMA of Roanoke Rapids for a total of no more than 48 in-center dialysis stations at BMA of Roanoke Rapids upon completion of the project.**
- 4. The certificate holder shall install plumbing and electrical wiring through the walls for no more than two home hemodialysis stations.**

## 5. Progress Reports

- a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.
  - b. The certificate holder shall complete all sections of the Progress Report form.
  - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.
  - d. The first progress report shall be due on September 1, 2025.
6. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

## C

The applicant proposes to develop a new dialysis facility dedicated to home hemodialysis and peritoneal dialysis training and support by relocating no more than two in-center dialysis stations and the entire home training program from BMA of Roanoke Rapids.

### **Capital and Working Capital Costs**

In Section Q, Form F.1a Capital Cost, page 104, the applicant projects the total capital cost of the project, as summarized below.

Capital Cost	Applicant FMC Boice-Willis Home, LLC	Total
Site Preparation	\$49,705	\$49,705
Construction/Renovation Contract	\$1,081,775	\$1,081,775
Architect/Engineering Fees	\$101,833	\$101,833
Medical Equipment	\$40,350	\$40,350
Furniture	\$92,740	\$92,740
Other Contingency	\$61,666	\$61,666
<b>Total Capital Cost</b>	<b>\$1,428,069</b>	<b>\$1,428,069</b>

In Section Q, pages 105, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on construction estimates provided by an in-

house real estate and construction team and its experience as one of the longest providers of dialysis services in the state.

In Section F, page 53, the applicant states there will be start-up costs of \$134,844 and initial operating costs of \$773,448 for total working capital of \$908,293. On pages 53-54, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the proposed working capital needs are based on reasonable and adequately supported assumptions based on the following:

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

### **Availability of Funds**

In Section F, page 54, the applicant states it will fund both the capital cost and the working capital cost with corporate accumulated reserves of Fresenius Medical Care Holdings, Inc., a majority owner of FMS Boice-Willis Home, LLC. In Exhibit F-2, the applicant provides a January 15, 2025 letter signed by the VP Corporate Tax North America for Fresenius Medical Care Holdings, Inc. confirming the proposal capital cost of the project, the availability of sufficient funds for both the capital and working capital costs, and committing the funds to this project development.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the letter of commitment provided in Exhibit F-2 of the application and Fresenius Medical Care Holdings, Inc. financial statements as of September 30, 2024.

### **Financial Feasibility**

The applicant provided pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Form F.2, pages 108-113, the applicant projects that revenues will exceed operating expenses in the first and second full fiscal years following completion of the project, as shown in the table below.

<b>Halifax County Home</b>	<b>1<sup>st</sup> Full FY CY2028</b>	<b>2<sup>nd</sup> Full FY CY2029</b>
Total # of Treatments	5,193	5,544
Total Gross Revenues (Charges)	\$32,670,920	\$34,880,416
Total Net Revenue	\$1,942,580	\$2,081,188
Average Net Revenue per Treatment	\$374	\$375
Total Operating Expenses (Costs)	\$1,791,606	1,866,280
Average Operating Expense per Treatment	\$345	\$337
<b>Net Income</b>	<b>\$150,974</b>	<b>\$214,908</b>

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q, pages 108-113. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- Charges and expenses are based on historical facility operations of nearby Edgecombe Home Dialysis and projected forward.
- Payor percentages are based on historical facility operations of BMA of Roanoke Rapids.
- Operating costs are based on Edgecombe Home Dialysis, a nearby freestanding home therapy facility.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital costs of the proposal for all the reasons described above.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

### **C**

The applicant proposes to develop a new dialysis facility dedicated to home hemodialysis and peritoneal dialysis training and support by relocating no more than two in-center dialysis stations and the entire home training program from BMA of Roanoke Rapids.

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

According to Table 9A on page 124 of the 2025 SMFP, there are two existing or approved dialysis facilities in Halifax County as shown in the following table:

Halifax County Home			
Facility	Certified stations of 12/31/2023	# of IC Patients 12/31/2023	Utilization Rate 12/31/2023
BMA of Roanoke Rapids	50	143	71.50%
FMC Dialysis Services of Halifax	19	47	61.84%
Total	69	190	68.84%

In Section G, page 58, the applicant explains why it believes its proposal would not result in the necessary duplication of existing or approved dialysis services in Halifax 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 Halifax County that are already being used and will continue to be used for HHD training and support services. These stations already have been approved and HHD and PD training and support services are already being offered. The applicant is merely proposing to relocate existing certified stations to a new location within the same county, less than five minutes from where services are already being offered, thus the proposed project will not duplicate any existing or approved services in Halifax County.”*

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area based on the following:

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

### **Conclusion**

The Agency reviewed the:

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

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

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



The applicant proposes to develop a new dialysis facility dedicated to home hemodialysis and peritoneal dialysis training and support by relocating no more than two in-center dialysis stations and the entire home training program from BMA of Roanoke Rapids.

On Form H referenced in Section Q, the applicant provides current and projected staffing for the proposed services, as illustrated in the following table.

Position	1 <sup>st</sup> FFY	2 <sup>nd</sup> FFY
	CY2027	CY2028
Administrator (FMC Clinic Manager)	0.25	0.25
Home Training Nurses	1.50	5.00
Technicians (PCT)	1.50	2.00
Dietician	0.50	0.33
Social Worker	0.50	0.33
Maintenance	0.15	0.25
Administration /Business Office	0.50	0.50
Other (FMC Director of Operations)	0.25	0.25
Other (FMC Chief Technician)	0.10	0.15
Other (FMC In-Service)	0.15	0.15
<b>Total</b>	<b>5.40</b>	<b>5.40</b>

Source: Section Q, Form H

The assumptions and methodology used to project staffing are provided immediately following Form H in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.4 in Section Q. In Section H, pages 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 states, in Form H Assumptions, that the number of FTE positions is a function of the number of stations available and the patient census to ensure quality care and maximize cost effectiveness.
- The applicant projects sufficient operating expenses for the staff proposed by the applicant.
- The applicant describes the required qualifications for staff, continuing education, and other training programs.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

## C

The applicant proposes to develop a new dialysis facility dedicated to home hemodialysis and peritoneal dialysis training and support by relocating no more than two in-center dialysis stations and the entire home training program from BMA of Roanoke Rapids.

### **Ancillary and Support Services**

In Section I, page 62, the applicant identifies the necessary ancillary and support services for the proposed services. In Section I, pages 62-67, the applicant explains how each ancillary and support service is or will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available because the applicant describes the structure in place at both the corporate level and the facility level for providing the necessary ancillary and support services.

### **Coordination**

In Section I, page 67, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit H. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant's parent company, Fresenius Medical Care, has existing relationships with local health care and social service providers.
- The applicant provides a letter from the medical director of the facility attesting to the relationship between the medical director's physician practice and the facility.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health

service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

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

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

NA

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

C

The applicant proposes to develop a new dialysis facility dedicated to home hemodialysis and peritoneal dialysis training and support by relocating no more than two in-center dialysis stations and the entire home training program from BMA of Roanoke Rapids.

In Section K, page 70, the applicant states that the project involves constructing 3,298 square feet of new space. Line drawings are provided in Exhibit K-2.

On page 12, the applicant identifies the proposed site and on pages 70-71 provides information about the current owner, zoning and special use permits for the site, and the availability of

water, sewer and waste disposal and power at the site. Supporting documentation is provided in Exhibit K-4. The site appears to be suitable for the proposed project based on the applicant's representations and supporting documentation.

On page 70, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following:

- The applicant has searched for existing rentable space which would be suitable for renovation and use for the dialysis facility. Finding an existing structure eliminates the cost of building new space. Renovations can be accomplished much more cost effectively than building a new space.

On page 71, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the following:

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

On pages 71-72, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and ... persons [with disabilities], which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
  - (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L, page 75, the applicant provides the historical payor mix during CY2023 for its existing services at BMA of Roanoke Rapids, as shown in the table below.

Primary Payor Source at Admission	BMA of Roanoke Rapids					
	In-center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-Pay	0.7	0.50%			0.1	0.26%
Insurance*	3.2	2.21%	2.0	21.80%	1.9	10.10%
Medicare*	124.2	86.85%	6.9	76.30%	16.8	88.55%
Medicaid*	10.9	7.64%	0.2	1.90%	0.00	0.00%
Other	4.0	2.80%	0.0	0.00%	0.2	1.10%
<b>Total</b>	<b>143.0</b>	<b>100.00%</b>	<b>9.0</b>	<b>100.00%</b>	<b>19.0</b>	<b>100.00%</b>

In Section L, pages 75-76, the applicant provides the following comparison of the population served:

BMA of Roanoke Rapids	Last Full Operating Year	
	Percentage of Total Patients Served	Percentage of the Population of the Service Area
Female	46.9%	51.9%
Male	53.1%	48.1%
Unknown		
64 and Younger	51.4%	80.2%
65 and Older	48.6%	19.8%
American Indian	1.71%	1.2%
Asian		1.2%
Black or African American	85.1%	42.1%
Native Hawaiian or Pacific Islander		0.1%
White or Caucasian	11.4%	53.4%
Other Race	1.7%	5.4%
Declined/ Unavailable		

### Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 76, the applicant states it has no such obligation.

The applicant further states during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against BMA of Roanoke Rapids.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

### **C**

In Section L, page 77, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

Halifax County Home Projected Payor Mix CY2029						
	IC		HH		PD	
Payment Source	# of Patients	% of Patients	# of Patients	% of Patients	# of Patients	% of Patients
Self-Pay	0.0	0.0%	0.0	0.00%	0.1	0.26%
Insurance*	0.0	0.0%	2.3	21.80%	2.9	10.10%
Medicare*	0.0	0.0%	8.0	76.30%	25.0	88.55%
Medicaid*	0.0	0.0%	0.2	1.90%	0.0	0.00%
Misc. (including VA)	0.0	0.0%	0.0	0.00%	0.3	1.10%
<b>Total</b>	<b>0.0</b>	<b>0.0%</b>	<b>10.4</b>	<b>100.00%</b>	<b>28.2</b>	<b>100.00%</b>

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

On page 77, the applicant provides the assumptions and methodology it uses to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical experience of the existing dialysis facility, BMA of Roanoke Rapids, from which HHD an PD patients will transfer from.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, pages 78-79, the applicant adequately describes the range of means by which patients will have access to the proposed services and provides supporting documentation in Exhibit L-4.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

The applicant proposes to develop a new dialysis facility dedicated to home hemodialysis and peritoneal dialysis training and support by relocating no more than two dialysis stations and the entire home training program from BMA of Roanoke Rapids.

In Section M, page 80, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M.2. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- The applicant provides documentation for their Healthcare Professional Training Agreement/Outreach initiatives as well as a confirmation letter expressing their intent to extend their services as a clinical training site for nursing students of a community college in the area.
- The applicant states it often receives requests to utilize the facility for health professional training programs and discusses the options it offers when it receives such an inquiry.

**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 and peritoneal dialysis training and support by relocating no more than two dialysis stations and the entire home training program from BMA of Roanoke Rapids.

On page 113, the 2025 SMFP defines the service area for dialysis stations as “...the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.” Thus, the service area for this facility consists of Halifax County. Facilities may serve residents of counties not included in their service area. According to Table 9A, on page 124 of the 2025 SMFP, there are two existing or approved dialysis facilities in Halifax County as shown in the following table:

Halifax County Home			
Facility	Certified stations of 12/31/2023	# of IC Patients 12/31/2023	Utilization Rate 12/31/2023
BMA of Roanoke Rapids	50	143	71.50%
FMC Dialysis Services of Halifax	19	47	61.84%
Total	69	190	68.84%

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 81, the applicant states:

*“The applicant does not expect this proposal to have any effect on the competitive climate in Halifax County. The applicant does not project to serve dialysis patients currently being served by another provider. The projected patient population for the Halifax County Home facility begins with the current home therapy patient population at BMA of Roanoke Rapids and projects growth of that population based on recent growth trends as discussed in Section C of this application ....”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 82, the applicant states:

*“...Fresenius Medical Care related facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid. The majority of our patients rely upon Medicare and Medicaid to cover the expense of their treatments.*

*...*

*Fresenius Medical Care related facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid.”*

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

Regarding the impact of the proposal on quality, in Section N, page 81, the applicant states:

*“Quality of care is always in the forefront at Fresenius Medical Care-related facilities. Quality care is not negotiable. Fresenius Medical Care, parent organization for this facility, expects every facility to provide high quality care to every patient at every treatment.”*

See also Section B of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 82, the applicant states:

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

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

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

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

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (19) Repealed effective July 1, 1987.

- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

On Form O, in Section Q, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 125 existing or approved kidney disease treatment facilities located in North Carolina.

In Section O, page 87, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents resulting in an Immediate Jeopardy violation that occurred in any of these facilities. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all 125 facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

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

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.

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

### **10A NCAC 14C .2203 PERFORMANCE STANDARDS**

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

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

(b) *An applicant proposing to increase the number of in-center dialysis stations in:*

- (1) *an existing dialysis facility; or*
- (2) *a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need*

*shall document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per station per week as of the end of the first full fiscal year of operation following certification of the additional stations.*

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

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

-C- This proposal is to develop a new dialysis facility dedicated to HHD and PD training and support services by relocating two existing dialysis stations and the entire home therapy program from BMA of Roanoke Rapids. In Section C, page 34, the applicant projects it will train 12 home hemodialysis patients on two stations for an average of six home hemodialysis patients per station per year by the end of the first fiscal year of operation following certification of the facility.

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

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

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

-C- In Section C, pages 34-35, the applicant provides the assumptions and methodology used to project utilization of the proposed facility by home hemodialysis patients.