

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: January 25, 2023

Findings Date: January 25, 2023

Project Analyst: Ena Lightbourne

Co-Signer: Gloria C. Hale

Project ID #: R-12268-22

Facility: Chowan Home Dialysis

FID #: 200027

County: Chowan

Applicant(s): FMS ENA Home, LLC

Project: Develop one dialysis station to be used exclusively for home hemodialysis training and support services

### 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.

NC

FMS ENA Home, LLC (hereinafter referred to as “the applicant” or “ENA Home”), proposes to develop one dialysis station at Chowan Home Dialysis, dedicated exclusively to home hemodialysis (HH). Chowan Home Dialysis is a dialysis home training facility that currently serves peritoneal patients only. Upon project completion, Chowan Home Dialysis will be certified for both HH and Peritoneal Dialysis (PD) training and support services.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

- Written comments
- Information publicly available during the review and used by the Agency

Bases on that review, the Agency concludes that the application is not conforming to this criterion because there is no county need determination in the 2022 State Medical Facilities Plan (SMFP) for any additional dialysis stations. Table 9B on page 135 of the 2022 SMFP shows there is a surplus of four dialysis stations in Chowan County. Adding an additional dialysis station would increase the surplus of dialysis stations. Home hemodialysis stations are certified dialysis stations and are included in the ESRD planning inventory.

- (2) Repealed effective July 1, 1987.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 one dialysis station at Chowan Home Dialysis, dedicated exclusively to HH. Upon project completion, Chowan Home Dialysis will be certified for HH and PD training and support services.

### **Patient Origin**

On page 115, the 2022 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located.*” Thus, the service area for this facility consists of Chowan County. Facilities may also serve residents of counties not included in their service area.

On page 25, the applicant states that Chowan Home Dialysis began offering services for PD patients on April 21, 2022. The applicant provides the historical patient origin for the period beginning April 21, 2022, through August 1, 2022.

<b>Chowan Home Dialysis Historical Patient Origin</b>		
	<b>04/21/2022 to 08/01/2022</b>	
	<b># of PD Patients</b>	<b>% of Total</b>
Chowan	4.0	36.4%
Martin	1.0	9.1%
Perquimans	2.0	18.2%
Tyrell	2.0	18.2%
Washington	2.0	18.2%
<b>Total</b>	<b>11.0</b>	<b>100.0%</b>

Source: Section C, page 25

The following table illustrates projected patient origin for the second full fiscal year.

<b>Chowan Home Dialysis Projected Patient Origin 2<sup>nd</sup> Full FY, CY 2025</b>				
<b>County</b>	<b>HH</b>		<b>PD</b>	
	<b># of Patients</b>	<b>% of Total</b>	<b># of Patients</b>	<b>% of Total</b>
Chowan	6.0	75.0%	7.1	50.3%
Bertie	1.0	12.5%	0.0	0.0%
Martin	0.0	0.0%	1.0	7.1%
Pasquotank	1.0	12.5%	0.0	0.0%
Perquimans	0.0	0.0%	2.0	14.2%
Tyrell	0.0	0.0%	2.0	14.2%
Washington	0.0	0.0%	2.0	14.2%
<b>Total</b>	<b>8.0</b>	<b>100.0%</b>	<b>14.1</b>	<b>100.0%</b>

Source: Section C, page 26

In Section C, pages 26-34 and Section Q, pages 94-101, the applicant provides the assumptions and methodology used to project its patient origin.

*Home Hemodialysis*

- Chowan Home Dialysis was approved as a freestanding peritoneal dialysis facility. BMA, co-parent of the applicant, and Eastern Nephrology Associates (ENA), are committed to increasing the home therapy penetration rate in Chowan County. Physicians from ENA serve chronic kidney disease patients and serve as a referral source for dialysis facilities. BMA facilities currently serve some dialysis patients in Chowan County.
- Chowan Home Dialysis was certified April 2022 (Project ID# R-11834-20) and has served 11 PD patients in the first four months of operation which will exceed 12.6 PD

patients by the end of the first operating year as projected in the original application. The applicant states that this demonstrates the commitment to increase home therapy penetration in the service area.

- The applicant identified patients in other counties that ENA serves from eastern North Carolina who could potentially choose home therapy services at Chowan Home Dialysis. However, the applicant assumes that patients prefer to be served in their home county. The applicant does not project growth for patients served in another county since home therapy patients do not have to travel to a center three times a week after training.
- The applicant cites data from the CMS Dialysis Compare website to illustrate the number of facilities in Chowan County offering home therapy. According to the data, Edenton Dialysis is the only dialysis facility operating in Chowan County and does not offer home therapy. The applicant states that Chowan Home Dialysis was not reflected on the website because the facility was certified in April 2022. The next closest facility that offers home therapy is 15.2 miles from Edenton Dialysis. The applicant assumes that the proposal will bring services closer to patients' residences, thus, enhancing access to care for patients in the service area.
- The applicant identified three HH patients who reside in Chowan County that receive services at FMC Pamlico in Beaufort County. The facility also served two PD patients residing in Chowan County who are interested in converting to HH. The applicant assumes that one of these PD patients will be required to change to HH in the near future. Additionally, the applicant identified two HH patients who reside in Bertie County and receive services at the Greenville Dialysis facility in Pitt County. The applicant assumes that at least one of these patients will transfer to Chowan Home Dialysis, as the facility would be closer to the patient's residence.
- The applicant identified three HH patients who reside in Pasquotank County receiving services at the FMC Pamlico facility in Beaufort County. The applicant assumes that at least one of these patients will transfer to Chowan Home Dialysis, as the facility would be closer to the patient's residence.
- The applicant received patient support letters from four home dialysis patients expressing interest in transferring their care to Chowan Home Dialysis.
- Based on the Executive Order to advance kidney health nationally, the applicant assumes that more patients will be referred for home dialysis.
- ENA Home has a history of achieving a home penetration greater than 45% and assumes that ENA Home can achieve a home penetration of at least 25% based on the number of counties across the state historically achieving a home penetration that exceeds 25%. The applicant identified the home penetration in a county similar to Chowan County. The applicant compares the following counties based on a similar ESRD patient population.

County	Home Penetration	ESRD Census
Swain	27.5%	51
Chowan	14.5%	55

Source: Section C, page 32

- Despite having an ESRD patient population 7.8% smaller than Chowan County, Swain County home penetration is 89.7% larger than Chowan County. The applicant states that this suggests that more Chowan County patients can dialyze at home.
- A physician at ENA supports the proposal and intends to refer patients for home therapies to the facility.
- The applicant relied on information from Edgecombe Home Dialysis (“Edgecombe”) to project future patient population at Chowan Home Dialysis, based on the following factors:
  - Edgecombe offers HH and PD training and support services. Chowan Home Dialysis is proposing to offer the same services.
  - Edgecombe relies on nephrology physicians of ENA for patient referrals and admissions as Chowan Home Dialysis is proposed to do.
  - Chowan Home Dialysis is proposed to have a medical director from the same practice.
  - Edgecombe is located approximately 69 miles away from the proposed Chowan Home Dialysis.

The applicant cites data from the 2020 through the proposed 2023 SMFPs, to illustrate Edgecombe County patient population growth, particularly among HH patients. The applicant states that Edgecombe County has been instrumental in creating changes within the ESRD patient population by referring patients for home therapies. The applicant assumes that Chowan Home Dialysis will have similar results.

<b>Edgecombe County ESRD Census</b>					
<b>SMFP</b>	<b>2020</b>	<b>2021</b>	<b>2022</b>	<b>Proposed 2023</b>	<b>CAGR</b>
Date of Data	<b>12/31/2018</b>	<b>12/31/2019</b>	<b>12/31/2020</b>	<b>12/31/2021</b>	
ESRD	247	247	264	279	4.14%

Source: Section C, page 32

<b>Edgecombe County Home Hemodialysis Census</b>					
<b>Data Source</b>	<b>2020 SMFP</b>	<b>2021 SMFP</b>	<b>2022 SMFP</b>	<b>Proposed 2023 SMFP</b>	<b>CAGR</b>
<b>Data Period</b>	<b>12/31/2018</b>	<b>12/31/2019</b>	<b>12/31/2020</b>	<b>12/31/2021</b>	
# Home Hemodialysis Patients	3	4	4	8	38.67%
% Increase		33.3%		100.0%	

Source: Section C, page 33

The following table illustrates the percentage of growth specific to Chowan County home therapy patients. The applicant states that this largely due the ENA’s commitment to increase home therapy penetration in Chowan County.

Chowan County				
SMFP	2021 SMFP	2022 SMFP	Proposed 2023 SMFP	2-Year CAGR for Home Therapy Patients
<b>Date of Data</b>	<b>12/31/2019</b>	<b>12/31/2020</b>	<b>12/31/2021</b>	47.2%
Home Patients	6	8	13	
ESRD Patients	48	55	51	
Home %	0.1250	0.1455	0.2549	

Source: Section C, page 33

- The applicant projects growth using the Five-Year Average Annual Change Rate (AACR) of 9.3% for Chowan County, as published in the 2022 SMFP.
- The project is projected to be certified as of December 31, 2023. The applicant projects the first operating year of the project will be January 1, 2024 - December 31, 2024, and the second operating year will be January 1, 2025 - December 31, 2025.

*Home Peritoneal Dialysis*

- The applicant projects growth using a rate higher than the Five-Year AACR for Chowan County. The applicant states that using a growth rate of 18.6% is reasonable based on the following factors:
  - The facility has exceeded the PD patient population for the first operating year within the first four months of operations.
  - The facility experienced a growth of at least two patients per month since the facility began operations.
  - The facility experienced more than a 100% increase in PD patients since April 2022.
- The project is projected to be certified as of December 31, 2023. The applicant projects the first operating year of the project will be January 1, 2024 - December 31, 2024, and the second operating year will be January 1, 2025 - December 31, 2025.

The applicant’s assumptions are reasonable and adequately supported based on the following:

- The applicant adequately demonstrates the growth of HH and PD patients in Chowan County and at other facilities serving home therapy patients.
- The applicant reasonably projects growth based on the actual growth in PD patients experienced at Chowan Home Dialysis.
- The applicant’s proposal supports the Executive Order to improve kidney health.

Analysis of Need

In Section C, pages 37-38, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- Developing an additional dialysis station dedicated to HH will enhance access to care as the need for home therapy grows.
- The proposed project will focus exclusively on HH and PD which will allow residents of Chowan County and surrounding areas access to HH training and support services.
- Failure to receive dialysis care will lead to the patient's demise.

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

- Actual growth in home patients exceeding the applicant's original projections demonstrated in Project ID# R-11834-20.
- The applicant's proposal will enhance access to HH services for Chowan County residents.

#### Projected Utilization

In Section C, page 35, and Section Q, page 102, the applicant provides projected utilization, as illustrated in the following table.

<b>Chowan Home Dialysis</b>	<b>HH Patients</b>
Begin with three Chowan County HH patients and two Chowan County PD patients expected convert to HH.	5.0
Add the two patients from other counties. This is the projected ending census for Interim Year One, December 31, 2023.	$5.0 + 2.0 = 7.0$
Project the Chowan County patient census forward for 12 months to December 31, 2024, increasing it by applying the Five-Year Chowan County AACR of 9.3%	$5.0 \times 1.093 = 5.5$
Add the two patients from other counties. This is the projected ending census for Operating Year One.	$5.5 + 2.0 = 7.5$
Project the Chowan County patient census forward for 12 months to December 31, 2025, applying the Five-Year AACR for Chowan County.	$5.5 \times 1.093 = 6.0$
Add the two patients from other counties. This is the projected ending census for Operating Year Two.	$6.0 + 2.0 = 8.0$



<b>Chowan Home Dialysis</b>	<b>PD</b>
Begin with the four existing Chowan County PD patients that the facility was serving as of August 1, 2022.	4.0
Project the Chowan County patient census forward for four months to December 31, 2022, using an 18.6% growth rate.	$4.0 \times (1.186/12 \times 4) + 4 = 4.2$
Add the seven patients from other counties. This is the projected census for Interim Year One.	$4.2 + 7.0 = 11.2$
Project the Chowan County patient census forward for 12 months to December 31, 2023, using an 18.6% growth rate.	$4.2 \times 1.186 = 5.0$
Add the seven patients from other counties. This is the projected census for Interim Year Two.	$5.0 + 7.0 = 12.0$
Project the Chowan County patient census forward for 12 months to December 31, 2024, using an 18.6% growth rate.	$5.0 \times 1.186 = 6.0$
Add the seven patients from other counties. This is the projected census for Operating Year One.	$6.0 + 7.0 = 13.0$
Project the Chowan County patient census forward for 12 months to December 31, 2025, using an 18.6% growth rate.	$6.0 \times 1.186 = 7.1$
Add the seven patients from other counties. This is the projected census for Operating Year Two.	$7.1 + 7.0 = 14.1$

In Section C, page 35 and Section Q, page 102, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The applicant begins with three Chowan County HH patients and two Chowan County PD patients expected to convert to HH.
- The applicant begins with the four PD patients that the facility was serving as of August 1, 2022.
- The applicant assumes that two HH patients and seven PD patients residing in other counties will transfer their care to Chowan Home Dialysis.
- The applicant projects growth of the Chowan County HH patient census using the Chowan County Five-Year AACR of 9.3%, as published in the 2022 SMFP.
- The applicant projects growth of the Chowan County PD patient census using a growth rate of 18.6%.
- The project is projected to be certified as of December 31, 2023. The first operating year of the project will be January 1, 2024 - December 31, 2024, and the second operating year will be January 1, 2025 - December 31, 2025.

The applicant projects to serve the following number of patients upon project completion.

	Operating Year 1	Operating Year 2
Home Hemodialysis	7.5	8.0
Peritoneal Dialysis	13.0	14.1

Source: Section C. page 36

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

- The applicant projects utilization based on the growth of home therapy in Chowan County and surrounding counties.
- Actual growth in home patients exceeds the applicant's original projections demonstrated in Project ID# R-11834-20.

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

In Section C. page 41, the applicant states:

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

The applicant provides the estimated percentage for each medically underserved group during the 2<sup>nd</sup> full fiscal year, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low-income persons	20.59%
Racial and ethnic minorities	91.18%
Women	44.12%
Persons with Disabilities	8.82%
Persons 65 and older	32.35%
Medicare beneficiaries	26.47%
Medicaid recipients	20.59%

Source: Section C, page 41

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The applicant relied on the Edgecombe Home Dialysis facility as a model for its patient population projections, based on the facility's similarity in services offered, referral and admission source, and its location to the proposed Chowan Home Dialysis.
- The applicant is an established provider of dialysis services across North Carolina currently providing services to underserved groups.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- 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.

- (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.

NA

The applicant does not propose to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

- (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.

NA

The applicant proposes to develop one dialysis station at Chowan Home Dialysis, dedicated exclusively to HH. Upon project completion, Chowan Home Dialysis will be certified for HH and PD training and support services.

In Section E, page 51, the applicant states that there were no other alternatives considered and any other alternative would not support the former President's Executive Order on Advancing American Kidney Health. On page 51, the applicant states:

*“At the present time, there are only two dialysis facilities operating in Chowan County, Edenton Dialysis and Chowan Home Dialysis. The applicant believes that offering home hemodialysis services to patients of Chowan County and surrounding counties would bring those services closer to the patient's residence, would be more convenient and would enhance access to care for the patients of the area.”*

However, the applicant does not adequately demonstrate that the alternative proposed in this application is the most effective alternative to meet the need because the application is not conforming to all other statutory and regulatory review criteria. An application that cannot be approved cannot be an effective alternative to meet the need.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

Based on that review, the Agency concludes that the application is not conforming to this criterion for the reason stated above. Therefore, the application is denied.

- (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 one dialysis station at Chowan Home Dialysis, dedicated exclusively to HH. Upon project completion, Chowan Home Dialysis will be certified for HH and PD training and support services.

## **Capital and Working Capital Costs**

In Section Q, page 105, the applicant projects the total capital cost of the project, as shown in the table below.

<b>Projected Capital Cost</b>	
Non-Medical Equipment	\$750
Furniture	\$3,000
<b>Total</b>	<b>\$3,750</b>

In Section Q, page 105, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on what is needed to operate the facility, such as patient chairs and the water treatment system.

## **Availability of Funds**

In Section F, page 52, the applicant states that the capital cost will be funded, as shown in the table below.

**Sources of Capital Cost Financing**

Type	FMS ENA Home, LLC	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$3,750	\$3,750
Bonds	\$0	\$0
Other	\$0	\$0
<b>Total Financing</b>	<b>\$3,750</b>	<b>\$3,750</b>

\* OE = Owner's Equity

On page 54, the applicant states that there will be no start-up costs or initial operating costs for the existing facility.

Exhibit F-2 contains a letter dated September 15, 2022, from the Senior Vice-President and Treasurer of Fresenius Medical Holdings, Inc., majority owner of FMS ENA Home, LLC, stating their commitment to fund the capital needs of the project through accumulated reserves. The letter states the Fresenius Medical Holdings' 2021 consolidated balance sheet reflected \$939 million in cash and over \$27.2 billion in total assets to fund the project.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the information provided in Section F and Exhibit F-2 of the application.

**Financial Feasibility**

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

Chowan Home Dialysis	1 <sup>st</sup> Full FY	2 <sup>nd</sup> Full FY
	CY2024	CY 2025
Total Treatments	2,921	3,145
Total Gross Revenues (Charges)	\$18,378,513	\$19,785,230
Total Net Revenue	\$1,152,554	\$1,240,994
Average Net Revenue per Treatment	\$395	\$395
Total Operating Expenses (Costs)	\$1,161,926	\$1,220,291
Average Operating Expense per Treatment	\$398	\$388
Net Income	(\$9,372)	\$36,004 [\$20,703]

Project Analyst calculation in brackets.

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q, page 109. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant provides reasonable assumptions in determining revenue and operating expenses in preparation of Forms F.2, F.3 and F.4.

- 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
- Written comments

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 costs are based on reasonable and adequately supported assumptions for all the reasons described above.
  - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
  - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

NC

The applicant proposes to develop one dialysis station at Chowan Home Dialysis, dedicated exclusively to HH. Upon project completion, Chowan Home Dialysis will be certified for HH and PD training and support services.

On page 115, the 2022 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located.*” Thus, the service area for this facility consists of Chowan County. Facilities may also serve residents of counties not included in their service area.

The table below lists the existing and approved facilities, certified stations, and utilization of dialysis facilities in Chowan County as of December 31, 2021, according to 2021 ESRD Data Collection Forms submitted to the Agency. There is one kidney disease treatment center providing dialysis services in Chowan County.

Facility Name	Certified Stations as of 12/31/2021	# IC Patients as of 12/31/2021	Utilization by Percent as of 12/31/2021	Patients Per Station Per Week
Edenton Dialysis	20	51	63.75%	2.55
Total	20	51		

Source: 2021 ESRD Data Collection Forms

In Section G, page 60, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Chowan County. The applicant states:

*“While the applicant is proposing to develop one dialysis station, the station would be used exclusively for home hemodialysis and should be excluded from the dialysis station inventory in Chowan County. At the time this application was prepared and submitted, Chowan Home Dialysis was the only dialysis facility offering home therapy services in Chowan County. The facility does not currently offer home hemodialysis; thus, the proposed project to develop one station to be exclusively used for home hemodialysis would not result in a duplication of the same existing or approved health services in Chowan County.”*

However, the applicant does not adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved services in the service area because the proposal would result in an additional dialysis station for which there is no county need determination. Thus, the addition of a dialysis station in Chowan County would increase an existing surplus of dialysis stations in Chowan County. An alternative method or policy for developing new dialysis stations that would be used exclusively for home hemodialysis training, and that would not require a need determination in the SMFP would need to be developed and approved by the State Health Coordinating Council.

### **Conclusion**

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is not 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 one dialysis station at Chowan Home Dialysis, dedicated exclusively to HH. Upon project completion, Chowan Home Dialysis will be certified for HH and PD training and support services.

In Section Q, pages 117-118, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Projected FTE Staff	
	Current	Projected
	As of 08/01/2022	2 <sup>nd</sup> Full FY CY 2025
Administrator (FMC Clinic Manager)	0.50	0.50
Home Training Nurse	1.00	2.00
Technicians (PCT)	0.00	1.00
Dietician	0.50	0.50
Social Worker	0.50	0.50
Maintenance	0.50	0.50
Administrative/Business Office	0.50	0.50
Other: FMC Director of Operations	0.33	0.33
Other: Chief Technician	0.10	0.10
Other: FMC In-Service	0.10	0.10
<b>TOTAL</b>	<b>4.03</b>	<b>6.03</b>

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.4. In Section H, pages 62-63, the applicant describes the methods to be 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 is proposing to offer a wide range of personnel benefits and competitive salaries to attract qualified staff.
- In response to the pandemic’s impact on staffing, parent company Fresenius Medical Care, has implemented initiatives such as, sign-on and retention bonuses, increased starting salaries and intensified recruiting efforts.
- New employees are required to complete a 10-week training program that includes safety precautions in addition to clinical training.



## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

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 one dialysis station at Chowan Home Dialysis, dedicated exclusively to HH. Upon project completion, Chowan Home Dialysis will be certified for HH and PD training and support services.

## **Ancillary and Support Services**

In Section I, page 64, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 64-69, 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.

## **Coordination**

In Section I, page 69, the applicant describes its existing and proposed relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on following:

- The applicant's established relationships with other physicians and hospitals in the area, which include Eastern Nephrology Associates Access Center, where ESRD patients may receive care.
- The applicant has agreements for lab services, hospital affiliation and transplant.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

- Written comments

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

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

NA

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

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

NA

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

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

NA

The applicant does not propose to construct any new space or renovate any existing space. Therefore, Criterion (12) is not applicable to this review.

(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;

NA

In Section L, page 76, the applicant states that Chowan Home Dialysis began operations on April 21, 2022, therefore, there is no historical payor mix to report for the previous full fiscal year.

(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 79, the applicant states:

*“The facility is not obligated under any applicable federal regulations to provide uncompensated care, community service, or access by minorities and persons with disabilities.”*

In Section L, page 79, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

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 79, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

Chowan Home Dialysis Projected Payor Mix 2 <sup>nd</sup> Full FY, CY 2025				
Payor Source	HH		PD	
	# of Patients	% of Total	# of Patients	% of Total
Self-Pay	0.0	0.00%	0.0	0.00%
Insurance*	1.6	20.67%	3.2	22.62%
Medicare*	6.3	79.33%	9.1	64.74%
Medicaid*	0.0	0.00%	0.6	4.08%
Other Misc. including VA	0.0	0.00%	1.2	8.56%
<b>Total</b>	<b>8.0</b>	<b>100.00%</b>	<b>14.1</b>	<b>100.00%</b>

\*Including any managed care plans.

Totals may not foot due to rounding.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 79.33% of total services will be provided to HH Medicare patients and 64.74% to PD Medicare patients, and 4.08% to PD Medicaid patients.

On pages 79-80, the applicant provides the assumptions and methodology used 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 based on the following:

- The applicant calculated payor mix based upon treatment volumes as opposed to the number of patients. The applicant considered the possible change in payor source during the fiscal year.
- Payor mix projections are based on Edgecombe Home Dialysis' historical facility performance which provides similar services.
- The applicant states that Medicaid HH patients will have access to the facility as evidenced by its Medicaid certification letter provided in Exhibit O-2.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

Based on that review, the Agency concludes that the application is conforming to this criterion based on 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, page 81, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

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 one dialysis station at Chowan Home Dialysis, dedicated exclusively to HH. Upon project completion, Chowan Home Dialysis will be certified for HH and PD training and support services.

In Section M, page 83, 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 following:

- Fresenius Medical Care facilities have a history of allowing health-related education and training programs visit the facility to observe the operation of the unit while patients receive treatment.

- The applicant provides a copy of a letter sent to the College of the Albemarle, encouraging the school to include Chowan Home Dialysis facility in their clinical rotations for nursing students.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

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.

NC

The applicant proposes to develop one dialysis station at Chowan Home Dialysis, dedicated exclusively to HH. Upon project completion, Chowan Home Dialysis will be certified for HH and PD training and support services.

The table below lists the existing and approved facilities, certified stations, and utilization of dialysis facilities in Chowan County as of December 31, 2021, according to 2022 ESRD Data Collection Forms submitted to the Agency. There is one kidney disease treatment center providing dialysis services in Chowan County.

Facility Name	Certified Stations as of 12/31/2021	# IC Patients as of 12/31/2021	Utilization by Percent as of 12/31/2021	Patients Per Station Per Week
Edenton Dialysis	20	51	63.75%	2.55
Total	20	51		

Source: 2022 ESRD Data Collection Forms

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 84, the applicant states:

*“The applicant does not project to serve dialysis patients currently being served by another provider. The projected patient population for the facility begins with patients who are currently being served at the facility and at other facilities owned or operated by Fresenius Medical Care and is grown by reasonable growth rates as discussed in Section C of this application.*

...

*This facility also has added value stemming from the strength of our relationship with nephrology physicians of Eastern Nephrology Associates. These nephrologists have been practicing in Chowan County and surrounding counties, serving the ESRD patients of the area for many years. The practice brings together the collaborative efforts of a team of very qualified nephrologists to provide care for the patients choosing to dialyze at Chowan Home Dialysis.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 85, the applicant states:

*“Approval of this application will ensure continued access to care for the patients; this proposal will ensure continued convenient, affordable access to care for the growing number of home dialysis patients.”*

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

Regarding the impact of the proposal on quality, in Section N, page 85, 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 O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 85, the applicant states:

*“All Fresenius related facilities in North Carolina have a history of providing dialysis services to the underserved population of North Carolina. The Form O identifies all Fresenius related operational and/or CON approved facilities across North Carolina. Each of those facilities has a patient population which includes low-income persons, racial or ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.”*

See also Section L of the application and any exhibits.

However, the applicant does not adequately describe the expected effects of the proposed services on competition in the service area and adequately demonstrate the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant does not adequately demonstrate that:

- 1) The proposal is cost effective because the applicant did not adequately demonstrate that the proposal would not result in an unnecessary duplication of existing and approved health services.

### **Conclusion**

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is not conforming to this criterion based on the reason 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, pages 120-124, 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 of this type of facility located in North Carolina.

In Section O, page 90, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents resulting in immediate jeopardy had not occurred in any of these facilities. After reviewing and considering information provided by the applicant, the applicant provided 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 one dialysis station dedicated to providing home training and support services for home hemodialysis patients. 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.